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## EU-JAV WP7

## VACCINE RESEARCH: PRIORITIES & FUNDING

## **FINAL REPORT**

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## LIST OF ABBREVATIONS

CHNRI: Child Health and Nutrition Research Initiative FHI: Folkehelseinstituttet (FHI) Inserm: Institut National de la Santé et de la Recherche Médicale





### I- Introduction

The EU-JAV aims to strengthen cooperation between European countries to fight vaccine preventable diseases. EU-JAV focuses on sharing best practices on national immunisation policies, delivering, and sharing concrete tools for stronger national response to vaccination challenges. As such, it will contribute to the implementation of the European Council recommendations on vaccine-preventable diseases.

One of the activities of the joint action is related to identifying mechanisms to define tools and methods for priority setting, to increase collaboration in vaccine and vaccination research and cooperation for funding these programmes among European member states.

The work package 7 (WP7) was organized as follows:

- <u>Task 7.1 Priorities for vaccine research and development (led by Inserm)</u>: its objective was to establish a process involving all relevant stakeholders to develop a concept and prototype research priority setting framework to identify critical needs and priorities in terms of vaccine and vaccination research aiming at increase vaccination coverage in Europe
- Task 7.2 Potential mechanisms to increase collaboration of funding and research cooperation (led by FHI): its specific purpose is to identify sustainable mechanisms to decrease funding fragmentation and increase the potential more collaboration and shared funding on common priorities.

Based on these two tasks, general objective of this WP was to propose some leads to elicit research priorities in Europe and simplify research funding mechanisms, with a final objective to propose a shared funding on common priorities among member states in the European Union.

The EU-JAV aims to strengthen European cooperation against vaccine-preventable diseases and improve population health. There is a need to strengthen interaction of immunization information systems to increase vaccine surveillance capabilities, a better understanding of vaccine forecasting, supply and improved preparedness, as well as a better understanding of best practices and interventions to improve confidence in vaccines. However, the findings from WP7 have not identified a clear awareness and interest in financing these strategic objectives.

The lack of funding of research and development (R&D) of vaccines for the prevention and control of emerging infectious diseases has been improved since the start of the EU-JAV and the enormous contribution of COVID-19 vaccine funding has resulted in deployment of COVID-19 vaccines to the high and middle-income countries during 2021.

However, research areas like support of real-world effectiveness of vaccines, implementation of new vaccines in national public health programmes, follow-up of safety signals, long-term safety





follow-up and better understanding mechanisms of vaccine hesitancy still lack funding and a coordinated approach among EU MS.

Indeed, the research funding system in Europe is very complex, involves many actors and is fragmented. With the great diversity of possible topics, in a context of limited resources, prioritizing research questions becomes a necessity. This selection process must be transparent, evidence-based and carried out rigorously, in accordance with best practices.

These two tasks are complementary, and the objective of the present report is to synthesize the overall WP7, present the main results and propose a small set of recommendations.





## II- Priorities for vaccine research and development

### 1) <u>Proposed framework and recommendations</u>

Based on literature review and expert's interviews, we proposed a prioritisation framework which we applied two times. The first prioritisation exercise occurred in January 2020 and concerned research priorities regarding four pilot vaccines (Influenza, Measles containing vaccine, HPV and pertussis). The second one concerned all vaccines but due to the context with a focus on Covid-19 vaccines.

The framework we propose in this report is a multi-criteria decision analysis inspired from the Child Health and Nutrition Research Initiative (CHNRI) by Rudan et al. Based on our experiences and advices from participating experts, it has been adapted throughout the project and particularly after comments from experts having participated in the first and second exercises.

The general principle of the framework is that each research proposition is assessed by a pool of experts using weighted criteria. This assessment lead to a ranking of research options which can be amended by a consensus expert during a discussion. It follows a series of step which are detailed below.

### A) Selecting managers and experts

- WP7.1 team constituted the managing team: it included one virologist with a previous experience of prioritization process as expert, one physician specialized in infectious diseases, one methodologist and a mathematician researcher who developed the tools for the next steps
- An external observer from WHO was mandated to advise on methodology and observe the meetings to ensure transparency
- Several steps of the process required participation of experts, and a great attention was paid to select experts from different fields, experiences and countries.

### Methodological recommendations:

- Ensure a diversity of expertise in the pool of experts
- Associate as far as possible an external observer to ensure transparency





### B) Definition of the context/scope of the process

- All the research questions focused on increasing vaccination coverage in the EU population and not on R & D to develop new vaccines
- An adaptation to the current pandemic context was needed, and as a result many of questions in the second exercise concerned COVID-19 vaccines

### Methodological recommendation:

The scope should be presented and explained as often as necessary in order to avoid submission of out-of-scope research questions and to support an objective and appropriate assessment from experts

- C) Identification of proposed health research options/questions
- Research options/questions to prioritize were identified through a web-based questionnaire sent to as many relevant stakeholders as identified
- Some of the submissions received were out of scope, too narrow or too broad, which highlights the need for being very clear with stakeholders consulted on what exactly is requested.

### Methodological recommendation:

As much as possible, use live events such as conferences to target relevant stakeholders to ensure good understanding of the scope of the process and increase response rate.





### D) Choice of criteria

- We initially propose 10 criteria to assess each research option/question
- After discussion with experts in charge of the definition of criteria, this list was amended twice: one criterium was reworded and another was eliminated

### Methodological recommendation:

As experts will assess each research option/question based of a set number of weighted criteria, it is very important to ensure that these criteria are unambiguous and understandable.

### Table 1: List of the seven final criteria

CRITERION 1: ANSWERABILITY (is the research question valid, feasible, acceptable?)

- 1. Would you say the research question is well framed and expected results are well defined?
- 2. Based on: (i) the level of existing research capacity in proposed research and (ii) the size of the gap from current level of knowledge to the proposed endpoints; would you say that a study can be designed to answer the research question and to reach the proposed expected results of the research?
- 3. Do you think that such a study would obtain ethical approval without any major concern?

CRITERION 2: EFFECTIVENESS – will results obtained lead to improved vaccine intervention and have sustainable effect over time on vaccine coverage?

- 1. Based on the best existing evidence and knowledge, would the intervention which would be developed/improved through proposed research be efficacious in increasing vaccine coverage?
- 2. Based on the best existing evidence and knowledge, would the intervention which would be developed/improved through proposed research be effective in increasing vaccine coverage in the current regulatory and data standard environment?
- 3. Do you think that the interventions which would be developed/improved through proposed research have prolonged or sustainable effectiveness over time on vaccine coverage (e.g. 10 years)?





CRITERION 3: DELIVERABILITY – can the results of the research be translated into policy (technically, financially and politically)?

- 1. Taking into account the technical complexity of sustainably improving vaccination coverage, are interventions based on evidence generated through this research likely to be delivered without major operational issues?
- 2. Taking into account the resources available to implement vaccine-related interventions would interventions based on evidence generated through the research project be affordable?
- 3. Taking into account government capacity and partnership requirements are interventions based on evidence generated through this research likely to be translated into policy?

CRITERION 4: EQUITY – will implementation of the intervention being researched increase equity?

- 1. Would you say that the underprivileged or particular target (e.g. pregnant women, migrants) groups or communities would be the most likely to benefit from the results of the proposed research after its implementation?
- 2. Would you say that the proposed research has the overall potential to improve equity in vaccine coverage in the long term (e.g. 10 years)?

CRITERION 5: GENERALIZATION- how generalized would the results be beyond the 4 pilot vaccines

- 1. In your opinion, is the research question specific of only one of the pilot vaccines?
- 2. If the research question is specific of one of the pilot vaccines, would you say that the results of the research question could be generalizable to other vaccines?
- 3. Would you say that the research question is of general relevance to potentially all vaccines used in EU vaccination programs (i.e. non-specific of any vaccine)?

CRITERION 6: TERRITORY – would interventions being researched be applicable to all EU countries and areas with less financial resources?

- 1. Would you say that the issue addressed by the research question is shared by several countries across the EU?
- 2. Would you say that the results of the research question would be generalizable to most countries in the EU?
- 3. Would you say that the results of the research question would be generalizable to areas with less financial resources and amenable to cross-border healthcare?





CRITERION 7: ACCESSIBILITY – how accessible would this research be for scientists and the public

- 1. Based on the best existing evidence and knowledge, would you say that results of the research would have a high potential of publication and dissemination, even if results are negative or inconclusive?
- 2. Would you say that results of the research would be easily understood by the general population?

### E) Weighting of criteria

- A web tool, developed by the Sztaki Institute, was sent to experts before the meeting. This allowed them to make pairwise comparisons by distributing 100% among two individual criteria according to their relative importance.
- A virtual meeting of the same experts allowed discussion of the respective weights obtained through the web tool. The weight of individual criteria was amended by consensus where necessary.

Methodological recommendation:

A meeting to get a to final consensus on weights was necessary to highlight potential misunderstanding regarding criteria.





### F) Final ranking

- A survey, developed by the SZTAKI Institute, was sent to experts before the meeting. It asked them to attribute for each research option/question a mark (from 0 to 3) for each criterion considered. The mark was to be interpreted as follows with respect to the criterion considered: 0: very bad / 1: rather bad / 2: rather good / 3: very good.
- A face-to-face meeting was organized to provide experts with the opportunity to discuss and express opposing views and to get to a consensus on the final ranking.

Methodological recommendation: This meeting need to be rigorously led to ensure that: - All experts express their opinion when necessary - All research questions will be discussed

## 2) <u>Results: two annual lists of research priorities</u>

### Table 2: Top-research priorities from the first exercise performed in 2020

- Assess and compare strategies for systematic measles vaccination catch-up in adolescence/adulthood for people who missed vaccination during childhood, in view of increasing immunity against measles in the population.

- Perform a review of evidence and impact of various social media interventions on the perception of HPV vaccination in adolescents and their close adult parents/guardians Explore the acceptability of the systematic use of tetravalent (DTPolio +Pertussis) vs trivalent (DTPolio) for revaccination during adulthood.

Investigate the effectiveness of various influenza vaccine formulations and products (LAIV, high-dose, adjuvanted, QIV vs TIV, cell-based vaccines, recombinant vaccines) in key target groups, i.e. (very) young children >65, frail and institutionalized older persons.
Evaluate the effectiveness in children of various ages, on protecting vulnerable persons (in particular elderly family members) against influenza.





- Investigate across Europe whether and how much authorizing pharmacists to administer seasonal influenza vaccine to the general population increases influenza vaccination coverage.

### Table 3: Top-research priorities from the second exercise in 2021

- Study whether – as compared with other new vaccines - the centralized purchasing and distribution method used in the EU has helped to reduce inequalities or access difficulties among and within countries and should therefore be generalized in case of a new pandemic.

- Generate evidence to optimize vaccine strategies for people with underlying conditions including immunodeficiency (additional dose, double dose, cocooning) – COVID-19

- Study which are the appropriate diagnostic tests to track persistence/decline

of immunity, and guide re-immunization policy in subsequent years? – COVID-19

- Analyse the different vaccination strategies implemented in European countries and model these strategies in terms of impact (on mortality, hospitalisation, economic indicators).

- Analyze the different vaccination strategies implemented in European countries and model these strategies in terms of impact (on mortality, hospitalisation, economic indicators). – COVID-19

- Analyze and detail the determinants of Covid-19 vaccine hesitancy and to assess whether they are different from those identified for other vaccines





# III-Mechanisms to increase collaboration in vaccine and<br/>vaccination research and collaboration for funding

Based on a literature review and a survey we describe EU-funding mechanisms and prioritised funding areas for vaccine and vaccination research among member states in the European union. The knowledge was gathered from different national organisations funding (R&D) on vaccines and vaccination research as well as selected European organisation known to be active in the field of funding for vaccination. The work focused on understanding the stakeholders and the organisations opinions on mechanisms to fund and collaborate on shared funding for common priorities and their opinion on joint mechanisms for funding of research in vaccination.

The survey was directed towards national research organisations and the literature review was focused on other multilateral organisations receiving funding from the European member states.

Throughout the project and during the COVID-19 pandemic R&D funding for vaccine research and development of COVID-19 vaccines followed. The main results can be summarised in three different areas presented below.

1) <u>EU- funding mechanisms and prioritised funding areas</u>

## Table 1: Areas of prioritised funding for national research organisations and multilateral organisations

- At the beginning of the EU-JAV, and prior to the covid-19 pandemic, the EU funding mechanisms and collaboration in vaccine research and development and vaccination research seemed very fragmented and complex.
- The national research organisations confirmed that funding of research and development as well as vaccination research is not evenly distributed along the value chain.
- Their key funding focus areas were:
  - General research and development of vaccines
  - o Basic research
  - Pre-clinical development





- Some of the organisations financed research on the four pilot vaccines and their priorities investigated in the research framework; influenza, pandemic influenza and HPV, but very few or none support research on measles, mumps, rubella or pertussis.
- Some of the organisations wanted to prioritize collaborations at EU-level for funding on vaccines for emerging infectious diseases, pandemic vaccines, or vaccines to be used during epidemic outbreaks.
- Others wanted to prioritize collaborations at EU-level, funding of specific vaccines in the immunization schedule for which more data on safety and follow-up is needed, and funding of influenza vaccine research due to low vaccine effectiveness.

Multilateral organisation receiving support from European member states:

- Several multilateral organizations additionally receive funding from the European member states in an uneven manner and are very active in financing vaccine research and development.
- Vaccines with a clear market potential and their development costs are most frequently funded by private sector. Early stage, basic science and late-stage implementation research often receive funding from public sector funding targeted at multilateral organisations.
- The establishment of CEPI has hugely improved funding of research and development of vaccines for the prevention and control of emerging infectious diseases included in the WHO R&D Blueprint list, but other organizations are also active in this field.
- Some EU member states use official development assistance (ODA) financing for this purpose, and these investments are neither aligned with the EU-JAV strategies nor the health strategies for public health purposes from the EU MS Ministries of Health.





### 2) <u>EU- collaboration mechanisms for vaccine research and</u> <u>development and vaccination research</u>

### Table 2: Cooperation mechanisms for national research organisations

- The most frequent mechanisms for collaborative funding are joint calls with other funders as well as bilateral and multilateral cooperation with research funding organisations from other countries.
- Mechanisms to increase cooperation:
  - There is a need for clear guidance and options for collaborations to be built into their governance system
  - $\circ\,$  A joint evaluation and selection process must be in place prior to the announcement of the call
  - $\circ$  Need for sufficient lead time to approve and agree on topics for calls for proposals
  - o Alignment of financial rules

Opinions on a potential future European mechanism

- Less than half of the national research organisations believed a potential future joint European mechanism (i.e., a JPI) would increase collaborative efforts in vaccine R&D and vaccination research.
- Voluntary mechanisms for collaboration could be more suitable.
- One area mentioned as a particular need for collaboration within the vaccine field was late-stage clinical trials and phase III/phase IV trials.

### 3) <u>COVID-19 vaccines as a paradigm for joint funding and new EU</u> instruments

### Table 3. Joint funding for vaccine research and development of COVID-19 vaccines





- The main differences between joint R&D funding prior to the COVID-19 pandemic and today have been the unprecedented speed on vaccine candidate's development, but also the massive public funding of the manufacturing process taken place with involvement from national and multinational organizations.
- EU and its members states has been the second largest contributor to the R&D investment after the United States and some of the EU countries have invested more separately than the EU institutions.
- The investment is both direct investment to R&D implementers and to public private partnership organizations, where mainly CEPI has been the largest receiver of the public funding to COVID-19 vaccine research and development. European investments in COVID-19 vaccines channeled through CEPI started in early 2020
- The European member states have primarily invested in pharmaceutical companies and ensured regional European manufacturing.
- The European member states have ensured sufficient supplies through a new instrument called Advance Purchase Agreements (APAs).
- The European Commission has addressed the need for new instruments in EU to address fragmentation of countermeasure R&D efforts in the EU and implemented a new Health Emergency Preparedness and Response Authority (HERA) department.
- HERA has been established during late 2021 and will continue to be developed in the years to come.
- Now the funding of HERA is anticipated from different existing EU financial instruments, such as EU4Health, Horizon Europe and the European Defense Fund. The plan is to benefit from mobilization of private funding as well as national budgets allocated to activities with the aim to support national plans for preparedness and response to health threats.
- A key task will be to promote research and innovation to develop effective, safe and affordable medical countermeasures, including diagnostics, therapeutics, and vaccines focused on key and emerging pathogens





## IV- <u>Sustainability</u>

The work under EU-JAV has allowed the articulation of a robust methodological framework for the prioritization of research projects on vaccines and vaccination as well as the identification of best practices for the implementation of this framework. This methodology can be used in the future, with relatively little adaptation, for other research topic prioritization exercises, ensuring sustainability of this EU-JAV deliverable.

The project has moreover conducted a thorough and extensive mapping of funding mechanisms in the EU, which can easily be refreshed in the coming years when and if necessary.

## V- Policy recommendations

- The purpose of the prioritization exercise and the owners of the results should be clarified upfront
- A minimum budget envelope to finance top-priority projects should be available before the start of the prioritization process
- Extensive outreach and community mobilization is needed to engage the right stakeholders into the process
- There is a need for better alignment on joint funding mechanisms for the strategic areas and top priority areas, such as research on real-world effectiveness of vaccines, implementation of new vaccines in national public health programmes and follow-up on long-term safety and safety signals
- It is of increasing importance to prioritize and finance research to better understand mechanisms of vaccine hesitancy in a coordinated approach among European member states
- Establishment and funding of HERA will be key to ensure better vaccine pandemic preparedness in Europe, but funding should also be made available to other global priority initiatives for vaccine R&D.





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## **ANNEXES**

Report WP7.1 Report WP7.2





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## Annual list of research priorities on vaccination, extending from pilot vaccines to cover most vaccines used in the EU (WP7.1)





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## LIST OF ABBREVATIONS

EU-JAV: European Joint Action on Vaccination

- HCW: Health Care Workers
- HPV: Human Papilloma Virus
- MCDA: Multiple Criteria Decision Analysis





## I- <u>Context</u>

The research funding system in Europe is very complex and involves many actors (1,2). With the great diversity of possible topics, in a context of limited resources, prioritizing research questions becomes a necessity. In the specific context of the EU Joint Action on Vaccination (EU-JAV), this selection process must be transparent, evidence-based and carried out rigorously, in accordance with best practices.

The objective of WP7.1 is to implement a process leading to evidence-based and transparent definition of research priorities in Europe in the field of vaccination research, focusing initially on four "pilot" pre-selected vaccines (pertussis, measles-containing combination vaccines, influenza and HPV), then expending to all vaccines used in the EU, including against COVID-19.

This process focused on <u>public health research aiming at improving vaccine coverage</u>, and not on development of novel vaccines. Many of the subjects to be prioritized therefore concerned epidemiology, human and social sciences as well as implementation research.

Based on review of the literature, the EU-JAV WP7 team decided to use a **multi-criteria decision analysis** methodology inspired by the Child Health and Nutrition Research Initiative (CHNRI). The overall methodology is presented in the Annex.

It followed several steps:

- 1. Selection of managers of the process
- 2. Scope definition of the process
- 3. Identification of key health research questions
- 4. Pre-selection of research options
- 5. Choice of criteria
- 6. Weighting of criteria
- 7. Final ranking during a face-to-face meeting

The description of steps 1 to 6 above has already been described in Deliverable 33. The present document refers to step 7 above and to the outcome of the face-to-face (through videoconference) meeting of experts, which allowed the preparation of a second ranked list of research priorities on vaccination. This meeting took place via Zoom in two different sessions: June, 16<sup>th</sup>, and July, 13<sup>th</sup>, 2021.





## II- Participants list

<u>Participating experts</u>: Richard Bergtrom (Sweden), Antonietta Filia (Italy), Nadia Khelef (France), Deborah Khursigara (Canada), Daniel Levy-Bruhl (France), Hannah Nohynek (THL, Finland), Agnès Saint-Raymond (France), Charlie Weller (England)

WP7.1 team: Jean-Daniel Lelièvre, Marie-Paule Kieny, Florence Francis, Sandor Bozoki, Zsombor Szadoczki

Observers: Anne-Marie Yazbeck (EC), Si Mehand Massinissa (WHO)

## III- Methods

All details concerning the method used were described in Deliverable 33.

- 1) <u>Preliminary steps to the meeting</u>
- The survey for question generation was circulated to European NITAGs, JAV partners, Vaccelerate project partners, the French advisory committee on Covid vaccine, the French strategical operational committee for Covid vaccination. Questions were requested which were either applicable to all vaccines used in the EU or particular to COVID-19 vaccines. Among the questions received, 8 questions corresponded to the former et 27 to the latter.
- Some of the submissions were comments more than research questions and were therefore screened out. This resulted into an initial list of 35 questions (Annex 1). The WP7.1 team sorted out the questions, merged those who were mostly similar and edited the language when necessary for harmonization purposes. A final list of 27 questions was then available for review and prioritization by experts (Annex 2).
- After previous year's ranking meeting, a decision was made to remove the criteria regarding epidemiology of disease because it led to confusion.
- New weights for the 7 remaining criteria were attributed by scaling up remaining criteria in a linear way.
- The same survey as the previous year, developed by the SZTAKI Institute was filled by experts individually before the final consensus meeting. The survey asked them to attribute for each research question a mark (from 0 to 3) for each of the 7 criteria considered. The mark was to be interpreted as follows: 0: very bad / 1: rather bad / 2:





rather good / 3: very good with respect to the criterion considered. The individual responses were consolidated for each question.

- The ranked list of research question was circulated at the beginning of the meeting. Below a bar graph showing the consolidated rating of all research proposals. Annex 3 presents the anonymized individual ratings for each question.



- Experts discussed the results of the individual ratings in order to reach a consensus (Table 1).

### 2) <u>Methodology for the meeting</u>

The objective of the meeting was to classify the research proposals submitted into three tiers. After review of the 8 highest-ranked questions, the lowest scored questions were addressed, and finally all remaining questions were discussed.

• Agreement was reached to review the ranking of the questions and group them in a final discussion according to their level of priority into three tiers (top priority, medium priority, no priority), without ordering for questions within a tier;





- Participants agreed to start discussing individual questions by order of ranking, based on the results of the survey (starting from the question ranked 1<sup>st</sup>).
- Finally, experts agreed by consensus on the final priority list.

## IV- <u>Results: final list of research priorities on vaccination</u>

The 27 questions sorted into three tiers are presented in Table 1 below. The invited observer confirmed at the end of the meeting that due process had been followed. Table 1: List of ranked research questions (not presented in order of priority)

### Tier 1 TOP priority list (not in order of priority)

- Study whether – as compared with other new vaccines - the centralized purchasing and distribution method used in the EU has helped to reduce inequalities or access difficulties among and within countries and should therefore be generalized in case of a new pandemic.

Generate evidence to optimize vaccine strategies for people with underlying conditions including immunodeficiency (additional dose, double dose, cocooning) – COVID-19

- Study which are the appropriate diagnostic tests to track persistence/decline

of immunity, and guide re-immunization policy in subsequent years? - COVID-19

- Analyse the different vaccination strategies implemented in European countries and model these strategies in terms of impact (on mortality, hospitalisation, economic indicators).

- Analyze the different vaccination strategies implemented in European countries and model these strategies in terms of impact (on mortality, hospitalisation, economic indicators). – COVID-19

- Analyze and detail the determinants of Covid-19 vaccine hesitancy and to assess whether they are different from those identified for other vaccines





### Tier 2 MEDIUM priority list (not in order of priority)

- Document, analyze and evaluate interventions to address social inequalities in vaccination with COVID-19 in various EU-countries.

- Study the propensity of the various vaccine types to lead to appearance of escape mutants – COVID-19

- Study the impact of refusal of vaccination by health professionals (by category) on the general population's choice to be vaccinated – COVID-19

- Analyze in various EU countries the perception and acceptability of the concept of benefit-risk balance: understanding, acceptability thresholds, according to the type of adverse effect, type of benefit (direct or indirect), age, etc. – COVID-19

- Study the influence of a future "vaccine passport" on the acceptance of vaccination (by type of population) – COVID-19

- Model the impact of non-vaccination of various percentages of health professionals on COVID-19 nosocomial infections.

- Evaluate the impact of digital health solutions to support access to vaccination.

- Perform HTA (Health technology assessment) of existing and future COVID-19 vaccines, with subgroup analysis (pediatrics, elderly, citizens with chronic disease) among the EU Member States over time.

- Explore among EU-countries, the reasons for changing vaccination refusal to acceptance. These can include, inter alia, perceived absence of transparency of negotiation, liability indemnification for producers, no-fault compensation provisions, and convenience of vaccination for daily life activities (travel, entertainement)

- Analyse the impact on uptake of different strategies by European MS (dedicated vaccination centers, hospitals, general practitioners, pharmacists, others)

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- Analyze the acceptability and preferences around COVID-19 vaccination among less than 18 (adolescents and children) and parents of adolescents or children, and young people aged 18-29 years.

- Analyse the impact of compulsory COVID-19 vaccination for various populations on vaccine coverage, number of cases, transmission, morbidity, nosocomial infection, mortality for different types of population in the light of the experience in Europe for other vaccines.

### Tier 3: Not a priority and/or out of scope research questions\*

- Analyze the relevance and feasibility of performing vaccine serologies either post or pre vaccination COVID19.

- Analyze the disadvantages in terms of compliance (analyzed by age-group) of 2-dose regimens in regard to coverage, compared to vaccines requiring only a single-dose – COVID-19

- Analyze social preferences which have been used in Europe to decide on whom to prioritize for COVID-19 vaccination? Analyze the impact on decisions of health vs economic considerations?

- Model the impact on vaccine availability and on the cost-effectiveness of the campaign of potential SARS-CoV-2 seropositivity testing before vaccination (with the objective of identifying people to whom only a single dose should be given or those who should receive a third dose).

- Analyze the pros/cons of compulsory COVID-19 vaccination (general or for HCWs) in light of the experience in Europe for other vaccines.

- Study whether the multimodal approach of WHO is an effective strategy to improve infection control safety/quality and vaccination coverage in Long term care facilities?

### Questions that have been already addressed by the scientific community





- Study what types of messages and communication strategies improves vaccine coverage in migrants – COVID-19

- Model the impact of vaccination of children (by age group) on the evolution of the pandemic taking into consideration various levels coverage in adults – COVID-19

## V- <u>Discussion</u>

This process described above allowed the WP7.1 team to establish a second list of European priorities regarding vaccination research. The framework developed in D33 was followed, with minor changes to improve the process: e.g. through greater attention to target those likely to propose research questions, better explanation of the prioritization criteria.

It is to be noted that this second exercise was impacted by the Covid-19 crisis: fewer research questions were obtained, and a majority of them were related to Covid-19 vaccines, attesting of the focus of the scientific community on the pandemic.

Due to the high international priority given to Covid-19 vaccines, some questions had already been addressed during the time between the collection of proposals and the meeting.

The final meeting was conducted through two videoconferences, which proved more challenging for the purpose of reaching a consensus than a real face-to-face meeting.

## VI- <u>Conclusion</u>

After a pilot process, the prioritisation framework designed by the WP7.1 team was used successfully to establish a second list of research priorities to increase vaccine coverage. Experts defined 6 top-priorities, 12 medium-priorities and 6 lower-priorities.

The prioritisation framework for establish research priorities in Europe was therefore validated and might be used in the future for similar purposes.

The list of top priorities was submitted through the 'Stakeholders' Targeted Consultation on **EU4health related priorities, strategic orientations and needs**' survey. The ranked priorities will moreover be disseminated through EU-JAV channels.





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## <u>ANNEXES</u>

### Annex 1: Initial list of 35 questions

### **General questions**

- 1. Evaluate the impact of digital health solutions to support access to vaccination
- 2. Study the impact of refusal of vaccination by health professionals (by category) on the population's choice to be vaccinated
- 3. Study whether non-parenteral vaccine administration (e.g. nasal, oral, patch) might decrease vaccine rejection in Europe
- 4. Is the multimodal approach of WHO an effective strategy to improve infection control safety/quality and vaccination coverage among the Long term care facilities? (*LTCFs*) and vaccination strategies. To implement the WHO core components for quality and safety improvement in health care (Core components of infection prevention and control programmes in health care) in LTCFS, with multimodal strategies to promote infection control and vaccination promotion in LTCFs against the pandemic/ other infectious diseases (influenzas, pneumococcus). Assess Pre- and post- intervention vaccine coverage among LTCFs.
- 5. Can education and screening improve vaccine coverage in immigrants? "Screening" of importing contagious diseases and vaccinations from immigrants of developing countries through major mediators in Europe. Surveillance and electronic data capture (registry) on different Immigrants groups assess social and educational level of Immigrants. Promote educational seminars among different migrant population to promote vaccination in difficult to reach facilities/ groups. Assess Pre- and post- intervention vaccine coverage among different immigrant groups.
- 6. How can we improve and harmonize the EU vaccine deployment plan? *Improvement and Harmonization of EU COVID-19 vaccine deployment infrastructure*. *Critical infrastructure to enable efficient distribution, dose administration, supply, distribution, and vaccination sites, locally and regionally*.
- 7. How can we increase the EU citizens trust for vaccination –the role of local liaisons. Increase public confidence in vaccines and vaccination educational programmes to achieve widespread and general acceptance locally and regionally (the importance of local liaison engagement). Promoting increased vaccination coverage of existing vaccines

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(e.g. H1N1, COVID-19) by local campaigns and engagement of local/regional liaisons (e.g general practitioners)

8. OSHA and vaccination in high risk workers. *in Promoting tetanus booster dose in specific high risk workers* 

### COVID-19 vaccine questions

### Social and human sciences

- 9. Analyse social preferences which have been used in Europe to decide on whom to prioritize for COVID-19 vaccination? Analyse the impact on decisions of health vs economic considerations?
- 10. Analyse the different vaccination strategies implemented in European countries and evaluation of these strategies in terms of impact (on mortality, hospitalisation, economic indicators)
- 11. Analyse the efficiency of strategies used in Europe to immunize marginalized and vulnerable populations
- 12. Analyse the disadvantages of 2-dose regimens in regard to coverage, compared to vaccines requiring only a single-dose?
- 13. Explore reasons to explain vaccination refusal? Was refusal definitive? If not, what motivated a change of decision?
- 14. Model the impact of vaccination of children (by age group) on the evolution of the pandemic
- 15. Model the impact of non-vaccination (of all, of health professionals) on COVID-19 herd immunity
- 16. Analyse the pros/cons of compulsory COVID-19 vaccination (general or for HCWs) in the light of the experience acquired in Europe for other vaccines
- 17. Study the influence of a future "vaccine passport" on the acceptance of vaccination (by type of population)
- 18. Study whether determinants of Covid-19 vaccine hesitancy are the same or different from those usually identified for other vaccines





- 19. Analyse the impact on the efficacy of the vaccination of the use of different strategies by European MS (dedicated vaccination centres, hospitals, general practitioners, pharmacists, others)
- 20. Study whether as compared with other new vaccines the centralized purchasing and distribution method used in the EU has helped to reduce inequalities or access difficulties among and within countries?
- 21. Analyse the impact of the non-fault compensation systems on the vaccine uptake and vaccine confidence in the EU MS. The research could focus on the analysis and comparison of the update of vaccination and the level of vaccine confidence in EU MS that introduced the non-fault compensation systems.
- 22. What the clinical financial and social HTA (Health technology assessment) assessment of the existing and future COVID-19 vaccines? Social-Economic analysis of vaccines and immunization programs benefits on the society. Health technology assessment-clinical and cost comparative effectiveness of COVID-19 vaccines. To implement HTA clinical and cost-effectiveness reports with subgroup analysis (pediatrics, elderly, citizens with chronic disease) among the Member States over time to assess the comparative effectiveness including against the COVID-19 variants of concern (VOCs).
- 23. Analyze the perception and acceptability of the concept of the benefit-risk balance: understanding, acceptability thresholds, according to the type of adverse effect, type of benefit (direct or indirect), age, etc.
- 24. Analyze the acceptability and preferences around COVID-19 vaccination (initial and long-term) among adolescents, parents of adolescents and young people aged 18-29 years.
- 25. Document, analyze and evaluate interventions to address social inequalities in vaccination (COVID-19)

### **Biological sciences**

- 26. Investigate the optimal use of booster shots to maximize protection and minimize adverse effects: interval between administrations, booster with a different product (same or different platform)
- 27. Study how long does vaccine-induced protection last, including against VOC? Does this protection involve protection against infection, or protection against mild disease, or protection against severe disease requiring hospitalisation? Is this protection similar across risk and age groups?





- 28. Study the propensity of the various vaccines types to lead to appearance of escape mutants, and whether these actually present a public health hazard
- 29. Investigate the safety of COVID vaccines in children
- 30. Study whether there any evidence of a deleterious interaction leading to enhanced disease when natural infection is acquired subsequent to vaccine-induced immunity, and if so, over what timescale? (months/year/years)
- 31. Study which are the appropriate diagnostic tests to track persistence/decline of immunity, and guide re-immunisation policy in subsequent years?
- 32. Model the impact on vaccine availability and on the cost of the campaign of potential SARS-CoV-2 seropositivity testing before vaccination (with the objective of identifying people to whom only a single dose should be given or those who should receive a third dose
- 33. Analyze heterologous vaccine regimens either with different platforms or by combining vaccines from the same platform (notion of interchangeability of mRNA vaccines for example)
- 34. Analyze the relevance and feasibility of performing vaccine serologies either post or pre vaccination COVID19
- 35. Define European guidelines to precisely define the different types of immunodeficiency states and their impact on the vaccine strategy (additional dose, double dose, cocooning)





### Annex 2: Final list of 27 questions

### **General questions**

- 1. Evaluate the impact of digital health solutions to support access to vaccination.
- 2. Study the impact of refusal of vaccination by health professionals (by category) on the general population's choice to be vaccinated.
- 3. Study whether non-parenteral vaccine administration (e.g. nasal, oral, patch) might increase vaccine uptake in Europe.
- 4. Study whether the multimodal approach of WHO is an effective strategy to improve infection control safety/quality and vaccination coverage in Long term care facilities?

### COVID-19 vaccine questions

#### Social and human sciences

- 5. Analyse social preferences which have been used in Europe to decide on whom to prioritize for COVID-19 vaccination? Analyse the impact on decisions of health vs economic considerations?
- 6. Analyse the different vaccination strategies implemented in European countries and evaluation of these strategies in terms of impact (on mortality, hospitalisation, economic indicators).
- 7. Analyse the efficiency of strategies used in Europe to immunize marginalized and vulnerable populations.
- 8. Study what types of messages and communication strategies improves vaccine vaccine coverage in migrants.
- 9. Analyse the disadvantages in terms of compliance (analysed by age-group) of 2-dose regimens in regard to coverage, compared to vaccines requiring only a single-dose?
- 10. Explore potential differences among EU countries in reasons to explain vaccination refusal? Was refusal definitive? If not, what motivated a change of decision?
- 11. Model the impact of vaccination of children (by age group) on the evolution of the pandemic taking into considerations various levels coverage in adults.




- 12. Model the impact of non-vaccination of various percentages of health professionals on COVID-19 nosocomial infections.
- 13. Analyse the pros/cons of compulsory COVID-19 vaccination (general or for HCWs) in the light of the experience in Europe for other vaccines.
- 14. Study the influence of a future "vaccine passport" on the acceptance of vaccination (by type of population)
- 15. Model the impact on vaccine availability and on the cost-effectiveness of the campaign of potential SARS-CoV-2 seropositivity testing before vaccination (with the objective of identifying people to whom only a single dose should be given or those who should receive a third dose).
- 16. Study whether determinants of Covid-19 vaccine hesitancy are the same or different from those usually identified for other vaccines.
- 17. Analyse the impact on the efficacy of the vaccination of the use of different strategies by European MS (dedicated vaccination centres, hospitals, general practitioners, pharmacists, others).
- 18. Study whether as compared with other new vaccines the centralized purchasing and distribution method used in the EU has helped to reduce inequalities or access difficulties among and within countries?
- 19. Analyse the impact of the non-fault compensation systems for Covid-19 vaccines on vaccine confidence in EU MS compared to influenza vaccine where this mechanism doesn't exist.
- 20. Model the clinical, financial and social HTA (Health technology assessment) of existing and future COVID-19 vaccines, with subgroup analysis (pediatrics, elderly, citizens with chronic disease) among the EU Member States over time.
- 21. Analyze in various EU countries the perception and acceptability of the concept of benefit-risk balance: understanding, acceptability thresholds, according to the type of adverse effect, type of benefit (direct or indirect), age, etc.
- 22. Analyze the acceptability and preferences around COVID-19 vaccination among adolescents, parents of children 12-18, parents of adolescents, and young people aged 18-29 years.





23. Document, analyze and evaluate interventions to address social inequalities in vaccination with COVID-19 in various EU-countries.

#### **Biological sciences**

- 24. Study the propensity of the various vaccines types to lead to appearance of escape mutants.
- 25. Study which are the appropriate diagnostic tests to track persistence/decline of immunity, and guide re-immunisation policy in subsequent years?
- 26. Analyze the relevance and feasibility of performing vaccine serologies either post or pre vaccination COVID19.
- 27. Generate evidence to optimize vaccine strategies for people with underlying conditions including immunodeficiency (additional dose, double dose, cocooning).





#### Annex 3: Initial individual ranking obtained through the survey

Q18	Study wheth distribution i and within c	er – as com method used ountries?	pared with ot I in the EU ha	her new vac is helped to	cines - the ce reduce inequa	ntralized pur alities or acc	chasing and ess difficulti	d es among
Expert	1. Answerability	2. Effectiveness	3. Deliverability	4. Equity	5. Generalization	6. Territory	7. Accessibility	Unweighted sum
1.	3	3	3	3	2	2	2	18
2.	1	3	3	3	3	3	3	19
3.	3	3	2	2	3	2	2	17
4.	2	1	2	1	0	3	1	10
5.								
6.	3	2	3	3	2	2	3	18
7.	3	3	3	3	3	3	3	21
8.	3	3	3	3	3	3	2	20
9.	3	3	3	3	3	3	3	21
average score	2,625	2,625	2,750	2,625	2,375	2,625	2,375	18
average difference from the average score	0,563	0,563	0,375	0,563	0,781	0,469	0,625	
maximal score	3	3	3	3	3	3	3	
minimal score	1	1	2	1	0	2	1	
maximal difference between experts' scores	2	2	1	2	3	1	2	

The best and worst marks are highlighted in green and red, respectively.

Q27	Generate e immunodefi	Generate evidence to optimize vaccine strategies for people with underlying conditions including immunodeficiency (additional dose, double dose, cocooning).								
Expert	1. Answerability	2. Effectiveness	3. Deliverability	4. Equity	5. Generalization	6. Territory	7. Accessibility	Unweighted sum		
1.	3	3	3	3	3	2	3	20		
2.	2	3	3	3	3	3	3	20		
3.	3	2	2	2	2	2	2	15		
4.	3	2	3	3	1	2	3	17		
5.	3	3	3	3	3			21 (15)		
6.	2	2	2	2	2	1	2	13		
7.	2	3	2	2	2	2	2	15		
8.	3	3	3	3	3	3	3	21		
9.	2	3	3	2	2	3	2	17		
average score	2,556	2,667	2,667	2,556	2,333	2,250	2,500	17,53		
average difference from the average score	0,494	0,444	0,444	0,494	0,593	0,563	0,500			
maximal score	3	3	3	3	3	3	3			
minimal score	2	2	2	2	1	1	2			
maximal difference between experts' scores	1	1	1	1	2	2	1			





Q7	Analyse ti population	he efficiency is.	of strategies	used in Euro	ope to immuni	ze marginal	ized and vul	nerable
Expert	1. Answerability	2. Effectiveness	3. Deliverability	4. Equity	5. Generalization	6. Territory	7. Accessibility	Unweighte sum
1.	3	3	2	3	2	3	3	19
2.	3	2	2	3	3	3	3	19
3.	3	3	2	3	2	2	2	17
4.	2	2	1	3	2	1	2	13
5.								
6.	3	3	3	3	3	2	3	20
7.	2	3	3	3	3	3	3	20
8.	2	2	2	3	2	2	2	15
9.	2	2	1	2	1	2	2	12
average score	2,50	2,50	2,00	2,88	2,25	2,25	2,50	16,88
average difference from the average score	0,50	0,50	0,50	0,22	0,56	0,56	0,50	
maximal score	3	3	3	3	3	3	3	
minimal score	2	2	1	2	1	1	2	
maximal difference between experts' scores	1	1	2	1	2	2	1	

Q6	Analyse the these strates	Analyse the different vaccination strategies implemented in European countries and evaluation of hese strategies in terms of impact (on mortality, hospitalisation, economic indicators).									
Expert	1. Answerability	2. Effectiveness	3. Deliverability	4. Equity	5. Generalization	6. Territory	7. Accessibility	Unweighted sum			
1.	3	3	2	3	3	3	3	20			
2.	3	2	3		3		3	19,6 (!5)			
3.	3	2	2	1	1	3	2	14			
4.	3	3	2	1	3			16,8 (15)			
5.											
6.	3	3	3	3	3	3	3	21			
7.	3	3	3	3	3	3	3	21			
8.	1	1	1		2	2	2	10,5 (16)			
9.	1	2	2	2	1	1	1	10			
average score	2,500	2,375	2,250	2,167	2,375	2,500	2,429	16,60			
average difference from the average score	0,750	0,625	0,563	0,833	0,781	0,667	0,653				
maximal score	3	3	3	3	3	3	3				
minimal score	1	1	1	1	1	1	1				
maximal difference between experts' scores	2	2	2	2	2	2	2				





Q23	Document, COVID-19	analyze and in various El	l evaluate intr J-countries.	erventions to	) address soc	ial inequaliti	as in vaccina	ition with
Expert	1. Answerability	2. Effectiveness	3. Deliverability	4. Equity	5. Generalization	6. Territory	7. Accessibility	Unweighted sum
1.	3	3	3	3	2	1	2	17
2.	2	3	2	3	3	1	2	16
3.	3	2	2	3	1	2	2	15
4.	1	2	1	3	1	1	2	11
5.	2	3	3	3	3			19,6 (15)
6.	2	2	2	3	2	1	2	14
7.	2	2	1	2	2	2	2	13
8.	3	3	2	3	3	3	3	20
9.	3	3	3	3	3	2	2	19
average score	2,333	2,556	2,111	2,889	2,222	1,625	2,125	15,86
average difference from the average score	0,593	0,494	0,593	0,198	0,691	0,625	0,219	
maximal score	3	3	3	3	3	3	3	
minimal score	1	2	1	2	1	1	2	
maximal difference between experts' scores	2	1	2	1	2	2	1	

Q16	Study whet usually ider	Study whether determinants of Covid-19 vaccine hesitancy are the same or different from those usually identified for other vaccines.								
Expert	1. Answerability	2. Effectiveness	3. Deliverability	4. Equity	5. Generalization	6. Territory	7. Accessibility	Unweighted sum		
1.	2	0	0	2	2	1	1	8		
2.	3	3	2	3	3	1	3	18		
3.	3	2	2	2	1	2	2	14		
4.	2	1	1	1	1	0	1	7		
5.	3	3	3	3	3			21 (15)		
6.	3	3	3	3	2	2	3	19		
7.	3	3	2	2	2	2	3	17		
8.	3	3	2	3	2	3	3	19		
9.	3	3	3	2	2	2	2	17		
average score	2,778	2,333	2,000	2,333	2,000	1,625	2,250	15,32		
average difference from the average score	0,346	0,889	0,667	0,593	0,444	0,719	0,750			
maximal score	3	3	3	3	3	3	3			
minimal score	2	0	0	1	1	0	1			
maximal difference between experts' scores	1	3	3	2	2	3	2			





Q21	Analyze in balance: un benefit (dire	various EU o iderstanding, act or indirect	ountries the p acceptability ), age, etc.	perception and thresholds,	nd acceptabili according to	ty of the cor the type of a	ncept of ben adverse effe	efit-risk ct, type of
Expert	1. Answerability	2. Effectiveness	3. Deliverability	4. Equity	5. Generalization	6. Territory	7. Accessibility	Unweighter sum
1.	2	2	2	2	2	2	3	15
2.	3		2	1	3	1	3	15,16 (!6
3.	3	1	1	1	0	2	1	9
4.	2	3	3	1	3	2	2	16
5.	3	3	3	3	3			21 (15)
6.	2	2	2	2	1	1	2	12
7.	2	2	2	1	2	2	2	13
8.	3	3	3	3	3	3	3	21
9.	2	2	3	3	3	3	3	19
average score	2,444	2,250	2,333	1,889	2,222	2,000	2,375	15,51
average difference from the average score	0,494	0,563	0,593	0,790	0,864	0,500	0,625	
maximal score	3	3	3	3	3	3	3	
minimal score	2	1	1	1	0	1	1	
maximal difference between experts' scores	1	2	2	2	3	2	2	

Q14	Study the i	Study the influence of a future "vaccine passport" on the acceptance of vaccination (by type of population).								
Expert	1. Answerability	2. Effectiveness	3. Deliverability	4. Equity	5. Generalization	6. Territory	7. Accessibility	Unweighted sum		
1.	2	3	2	1	3	2	3	16		
2.	2	2	2	1	2	1	3	13		
3.	3	3	2	1	2	3	2	16		
4.	2	2	3	1	0	1	2	11		
5.	2							14 (11)		
6.	2	2	2	2	2	1	2	13		
7.	3	3	3	2	3	2	3	19		
8.	3	3	3	2	2	3	3	19		
9.	2	2	2	2	2	2	2	14		
average score	2,333	2,500	2,375	1,500	2,000	1,875	2,500	15,08		
average difference from the average score	0,444	0,500	0,469	0,500	0,500	0,656	0,500			
maximal score	3	3	3	2	3	3	3			
minimal score	2	2	2	1	0	1	2			
maximal difference between experts' scores	1	1	1	1	3	2	1			





Q12	Model the in nosocomial	npact of non- infections.	vaccination o	of various pe	rcentages of t	health profe	ssionals on (	COVID-19
Expert	1. Answerability	2. Effectiveness	3. Deliverability	4. Equity	5. Generalization	6. Territory	7. Accessibility	Unweighter sum
1.	2	3	3	3	3	1	2	17
2.	1	2	2	1	1	1	3	11
3.	3	2	2	1	1	2	2	13
4.	2	1	2	1	1	1	1	9
5.	3		3					21 (12)
6.	2	2	2	2	2	2	2	14
7.	3	2	2	2	2	2	2	15
8.	3	3	3	3	3	3	3	21
9.	2	3	3	3	3	2	2	18
average score	2,333	2,250	2,444	2,000	2,000	1,750	2,125	14,90
average difference from the average score	0,593	0,563	0,494	0,750	0,750	0,563	0,438	
maximal score	3	3	3	3	3	3	3	
minimal score	1	1	2	1	1	1	1	
maximal difference between experts' scores	2	2	1	2	2	2	2	

Q20	Model the cl COVID-19 v among the E	Model the clinical, financial and social HTA (Health technology assessment) of existing and future COVID-19 vaccines, with subgroup analysis (pediatrics, elderly, citizens with chronic disease) among the EU Member States over time.							
Expert	1. Answerability	2. Effectiveness	3. Deliverability	4. Equity	5. Generalization	6. Territory	7. Accessibility	Unweighted sum	
1.	1	1	2	0	2	1	1	8	
2.	3	2	3	2	3	1	3	17	
3.	2	2	3	2	1	2	2	14	
4.	2	1	2	1	2	2	2	12	
5.	3	3	3	3	3			21 (15)	
6.	3	3	3	3	2	2	3	19	
7.	3	3	3	3	3	3	3	21	
8.	3	3	2	3	3	2	2	18	
9.	1	1	1	1	1	1	1	7	
average score	2,333	2,111	2,444	2,000	2,222	1,750	2,125	14,99	
average difference from the average score	0,741	0,790	0,617	0,889	0,691	0,563	0,656		
maximal score	3	3	3	3	3	3	3		
minimal score	1	1	1	0	1	1	1		
maximal difference between experts' scores	2	2	2	3	2	2	2		





Q10	Explore potr refusal defir	ential differen hitive? If not,	ices among 6 what motivate	EU countries ed a change	in reasons to of decision?	explain vac	cination refu	ısal? Was
Expert	1. Answerability	2. Effectiveness	3. Deliverability	4. Equity	5. Generalization	6. Territory	7. Accessibility	Unweighted sum
1.	2	3	3	3	3	1	2	17
2.	1				1	1		7 (!3)
3.	3			1	1	2	2	12,6 (!5)
4.	2	2	1	2	1	1	1	10
5.	3		3	3				21 (13)
6.	3	3	2	3	2	2	3	18
7.	2	3	3	3	1	2	2	16
8.	3	3	3	2	3	3	3	20
9.	0	1	1	1	1	0	1	5
average score	2,111	2,500	2,286	2,250	1,625	1,500	2,000	14,27
average difference from the average score	0,790	0,667	0,816	0,750	0,781	0,750	0,571	
maximal score	3	3	3	3	3	3	3	
minimal score	0	1	1	1	1	0	1	
maximal difference between experts' scores	3	2	2	2	2	3	2	

Q17	Analyse t Europear others).	Analyse the impact on the efficacy of the vaccination of the use of different strategies by European MS (dedicated vaccination centres, hospitals, general practitioners, pharmacists, others).								
Expert	1. Answerability	1. 2. 3. 1. Effectiveness 3. Deliverability Equity Generalization 7. Unwe								
1.	3	3	2	3	3	3	2	19		
2.	1	3	2	3	3	1	3	16		
3.	2	1	2	1	2	2	2	12		
4.	2	2	1	2	1	2	2	12		
5.										
6.	2	2	2	2	1	1	2	12		
7.	2	3	2	1	2	2	2	14		
8.	3	3	3	3	3	3	3	21		
9.	1	2	2	2	1	1	2	11		
average score	2,000	2,375	2,000	2,125	2,000	1,875	2,250	14,63		
average difference from the average score	0,500	0,625	0,250	0,656	0,750	0,656	0,375			
maximal score	3	3	3	3	3	3	3			
minimal score	1	1	1	1	1	1	2			
maximal difference between experts' scores	2	2	2	2	2	2	1			





Q15	Model the potential S people to v	impact on va ARS-CoV-2: whom only a	ccine availab seropositivity single dose s	ility and on t testing befo hould be giv	he cost-effect re vaccinatior en or those w	tiveness of the old with the old with the old with the old read to the old read to the should read to the old read to the should read to the old read to the o	he campaign bjective of id aceive a third	n of lentifying d dose).
Expert	1. Answerability	2. Effectiveness	3. Deliverability	4. Equity	5. Generalization	6. Territory	7. Accessibility	Unweighte sum
1.	1	2	0	1	2	1	2	9
2.	2	3	3		3	2	3	18,67 (!6
3.	2	3	2	2	3	3	2	17
4.	3	3	2	1	0	1	2	12
5.								
6.	3	3	3	3	2	2	3	19
7.	2	3	2	1	2	2	2	14
8.	3	3	3	2	2	3	3	19
9.	1	1	1	1	1	1	1	7
average score	2,125	2,625	2,000	1,571	1,875	1,875	2,250	14,32
average difference from the average score	0,656	0,563	0,750	0,653	0,688	0,656	0,563	
maximal score	3	3	3	3	3	3	3	
minimal score	1	1	0	1	0	1	1	
maximal difference between experts' scores	2	2	3	2	3	2	2	

Q22	Analyze the acceptability and preferences around COVID-19 vaccination among adolescents, parents of children 12-18, parents of adolescents, and young people aged 18-29 years.									
Expert	1. Answerability	2. Effectiveness	3. Deliverability	4. Equity	5. Generalization	6. Territory	7. Accessibility	Unweighted sum		
1.	0	1	1	2	2	1	2	9		
2.	3	2	2	1	1	1	3	13		
3.	3	2	2	2	1	2	2	14		
4.	2	2	2	1	0	2	3	12		
5.	3	3	3	3				21 (14)		
6.	3	3	3	3	2	2	3	19		
7.	2	2	1	2	2	2	2	13		
8.	3	3	2	2	2	3	3	18		
9.	2	2	2	2	2	2	2	14		
average score	2,333	2,222	2,000	2,000	1,500	1,875	2,500	14,43		
average difference from the average score	0,741	0,519	0,444	0,444	0,625	0,438	0,500			
maximal score	3	3	3	3	2	3	3			
minimal score	0	1	1	1	0	1	2			
maximal difference between experts' scores	3	2	2	2	2	2	1			





Q3	Study wh vaccine u	Study whether non-parenteral vaccine administration (e.g. nasal, oral, patch) might increase vaccine uptake in Europe.									
Expert	1. Answerability	2. Effectiveness	3. Deliverability	4. Equity	5. Generalization	6. Territory	7. Accessibility	Unweighte sum			
1.	3	3	3	3	2	3	3	20			
2.	1		2	2	3	2	2	14 (!6)			
3.	2	1	1	1	3	2	3	13			
4.	3	1	1	2	0	3	2	12			
5.											
6.	2	2	2	2	2	2	2	14			
7.	3	2	1	1	2	2	2	13			
8.	2	1	2	2	3	2	2	14			
9.	3	3	3	2	2	2	2	17			
average score	2,375	1,857	1,875	1,875	2,125	2,250	2,250	14,61			
average difference from the average score	0,625	0,735	0,656	0,438	0,656	0,375	0,375				
maximal score	3	3	3	3	3	3	3				
minimal score	1	1	1	1	0	2	2				
maximal difference between experts' scores	2	2	2	2	3	1	1				

Q13	Analyse the pros/cons of compulsory COVID-19 vaccination (general or for HCWs) in the light of the experience in Europe for other vaccines.									
Expert	1. Answerability	2. Effectiveness	3. Deliverability	4. Equity	5. Generalization	6. Territory	7. Accessibility	Unweighted sum		
1.	2	3	1	3	2	2	2	15		
2.	1	1	2	1	2	1	1	9		
3.	2	2	2		3	3	3	17,5		
4.	2	2	2	2	1	0	3	12		
5.	3				3			21 (12)		
6.	3	3	3	3	3	2	3	20		
7.	2	2	2	1	1	2	2	12		
8.	3	3	3	2	2	3	3	19		
9.	1	1	2	2	1	1	2	10		
average score	2,111	2,125	2,125	2,000	2,000	1,750	2,375	14,49		
average difference from the average score	0,593	0,656	0,438	0,571	0,667	0,813	0,625			
maximal score	3	3	3	3	3	3	3			
minimal score	1	1	1	1	1	0	1			
maximal difference between experts' scores	2	2	2	2	2	3	2			





QB	Study wh migrants.	at types of m	essages and	communical	tion strategie	s improves v	vaccine cove	rage in
Expert	1. Answerability	2. Effectiveness	3. Deliverability	4. Equity	5. Generalization	6. Territory	7. Accessibility	Unweighte sum
1.	2	3	2	3	2	2	2	16
2.	3	3	2	3	3	1	3	18
3.	2	3	2	2	1	2	2	14
4.	2	2	2	3	2	2	1	14
5.	2	2	2	3				15,75 (14
6.	2	2	2	3	2	1	2	14
7.	2	2	2	3	2	1	3	15
8.	2	2	1	3	2	2	2	14
9.	1	1	1	2	1	1	1	8
average score	2,000	2,222	1,778	2,778	1,875	1,500	2,000	14,15
average difference from the average score	0,222	0,519	0,346	0,346	0,438	0,500	0,500	
maximal score	3	3	2	3	3	2	3	
minimal score	1	1	1	2	1	1	1	
maximal difference between experts' scores	2	2	1	1	2	1	2	

Q11	Model the im into consider	pact of vacci ation various	ination of chil levels cover	dren (by age age in adults	e group) on th 3.	e evolution	of the pande	emic taking
Expert	1. Answerability	2. Effectiveness	3. Deliverability	4. Equity	5. Generalization	6. Territory	7. Accessibility	Unweighted sum
1.	2	2	2	3	3	2	3	17
2.	3	3	2	1	1	1	3	14
3.	3	2	2	1		2	2	14 (!6)
4.	3	2	3	2	1	1	3	15
5.				3				21 (11)
6.	2	2	3	2	2	2	3	16
7.	3	3	2	2	2	2	2	16
8.	2	2	2	2	2	2	2	14
9.	1	1	1	1	1	0	1	6
average score	2,375	2,125	2,125	1,889	1,714	1,500	2,375	14,10
average difference from the average score	0,625	0,438	0,438	0,593	0,612	0,625	0,625	
maximal score	3	3	3	3	3	2	3	
minimal score	1	1	1	1	1	0	1	
maximal difference between experts' scores	2	2	2	2	2	2	2	





Q4	Study whi control sa	ether the mu afety/quality a	timodal appr and vaccination	oach of WH	O is an effecti in Long term	ve strategy care facilitie	to improve in es?	nfection
Expert	1. Answerability	2. Effectiveness	3. Deliverability	4. Equity	5. Generalization	6. Territory	7. Accessibility	Unweighte sum
1.	2	1	1	2	2	2	2	12
2.	2	2	1	2	3	1	2	13
3.								
4.	0							0 (!1)
5.								
6.	3	3	3	3	3	3	3	21
7.	2	2	2	1	2	1	2	12
8.	1	1	2		2	2	1	10,5 (16)
9.	3	3	3	3	3	3	3	21
average score	1,857	2,000	2,000	2,200	2,500	2,000	2,167	14,72
average difference from the average score	0,776	0,667	0,667	0,640	0,500	0,667	0,556	
maximal score	3	3	3	3	3	3	3	
minimal score	0	1	1	1	2	1	1	
maximal difference between experts' scores	3	2	2	2	1	2	2	

Q9	Analyse the regard to co	disadvantage verage, comp	as in terms of pared to vacc	i compliance ines requirin	(analysed by g only a singl	/age-group) ie-dose?	of 2-dose re	egimens in
Expert	1. Answerability	2. Effectiveness	3. Deliverability	4. Equity	5. Generalization	6. Territory	7. Accessibility	Unweighted sum
1.	3	2	3	3	1	2	3	17
2.	0	0	0		0	0	0	0 (!6)
3.	3	2	2	2	1	2	2	14
4.	1	1	1	2	2	3	2	12
5.	3	3	3	3	3			21 (15)
6.	2	3	3	3	2	2	2	17
7.	2	2	0	1	0	2	2	9
8.	3	3	3	2	3	3	3	20
9.	2	2	2	2	2	2	2	14
average score	2,111	2,000	1,889	2,250	1,556	2,000	2,000	13,81
average difference from the average score	0,790	0,667	1,037	0,563	0,938	0,500	0,500	
maximal score	3	3	3	3	3	3	3	
minimal score	0	0	0	1	0	0	0	
maximal difference between experts' scores	3	3	3	2	3	3	3	





Q5	Analyse so COVID-19	Analyse social preferences which have been used in Europe to decide on whom to prioritize for COVID-19 vaccination? Analyse the impact on decisions of health vs economic considerations?									
Expert	1. Answerability	2. Effectiveness	3. Deliverability	4. Equity	5. Generalization	6. Territory	7. Accessibility	Unweighter sum			
1.	3	2	2	3	3	3	1	17			
2.	0							0 (!1)			
3.	3	1	3	1	0	2	2	12			
4.	1	1	2	2	1	2	3	12			
5.											
6.	3	3	3	3	3	3	3	21			
7.	2	3	3	3	3	3	3	20			
8.	1	1	1		1	1		7 (15)			
9.	1	1	2	2	2	1	1	10			
average score	1,750	1,714	2,286	2,333	1,857	2,143	2,167	14,25			
average difference from the average score	1,000	0,816	0,612	0,667	1,020	0,735	0,833				
maximal score	3	3	3	3	3	3	3				
minimal score	0	1	1	1	0	1	1				
maximal difference between experts' scores	3	2	2	2	3	2	2				

Q2	Study the population	Study the impact of refusal of vaccination by health professionals (by category) on the general population's choice to be vaccinated.									
Expert	1. Answerability	2. Effectiveness	3. Deliverability	4. Equity	5. Generalization	6. Territory	7. Accessibility	Unweighted sum			
1.	3	2	1	2	1	2	1	12			
2.	1	1	1	1	1	1	1	7			
3.	2	2	2	1	3	2	2	14			
4.	3	1	2	3	2	3	2	16			
5.	2	3			2			16,33 (13)			
6.	2	2	2	2	2		2	14 (16)			
7.	3	2	1	1	0	1	2	10			
8.	3	3	3	3	3	3	3	21			
9.	1	2	2	2	2	1	1	11			
average score	2,222	2,000	1,750	1,875	1,778	1,857	1,750	13,23			
average difference from the average score	0,691	0,444	0,563	0,656	0,741	0,735	0,563				
maximal score	3	3	3	3	3	3	3				
minimal score	1	1	1	1	0	1	1				
maximal difference between experts' scores	2	2	2	2	3	2	2				





Q19	Analyse the confidence	he impact of e in EU MS o	the non-fault compared to	compensatio influenza vao	on systems fo ccine where th	r Covid-19 v nis mechanis	accines on am doesn't e	vaccine exist.
Expert	1. Answerability	2. Effectiveness	3. Deliverability	4. Equity	5. Generalization	6. Territory	7. Accessibility	Unweighte sum
1.	2	1	2	2	3	2	1	13
2.	2	2	3	2	3	2	3	17
3.	3	2	3	1	3	2	2	16
4.	1	1	2	0	0	2	0	6
5.								
6.	2	2	2	2	1	1	2	12
7.	2	2	1	1	2	2	2	12
8.	2	2		3			2	15,75 (14
9.	1	2	1	1	2	1	2	10
average score	1,875	1,750	2,000	1,500	2,000	1,714	1,750	12,59
average difference from the average score	0,438	0,375	0,571	0,750	0,857	0,408	0,625	
maximal score	3	2	3	3	3	2	3	
minimal score	1	1	1	0	0	1	0	
maximal difference between experts' scores	2	1	2	3	3	1	3	

Q1	Ev	Evaluate the impact of digital health solutions to support access to vaccination.								
Expert	1. Answerability	2. Effectiveness	3. Deliverability	4. Equity	5. Generalization	6. Territory	7. Accessibility	Unweighter sum		
1.	2	2	2	2	2	2	2	14		
2.	3	3	2	1	3	1	3	16		
3.	2	2	3	2	3	3	2	17		
4.	1	3	1	1	2	1	3	12		
5.	3	3		2	2			17,5 (14)		
6.	3	2	2	2	2		3	16,33 (16		
7.	3	3	3	2	3	2	3	19		
8.	2	2	2		3	2	2	15,17 (16		
9.	2	2	1	2	1	1	1	10		
average score	2,286	2,429	1,833	1,714	2,143	1,600	2,333	14,95		
average difference from the average score	0,612	0,490	0,556	0,408	0,490	0,720	0,667			
maximal score	3	3	3	2	3	3	3			
minimal score	1	2	1	1	1	1	1			
maximal difference between experts' scores	2	1	2	1	2	2	2			





Q26	Analyze the relevance and feasibility of performing vaccine serologies either post or pre vaccination COVID19.							
Expert	1. Answerability	2. Effectiveness	3. Deliverability	4. Equity	5. Generalization	6. Territory	7. Accessibility	Unweighted sum
1.	0	1	1	1	1	1	1	6
2.	1			1	3		3	14 (!4)
3.	2	2	2	1	1	2	2	12
4.	1	1	3	1	0	2	2	10
5.								
6.	2	1	1	1	1	2	2	10
7.	2	2	2	1	2	2	2	13
8.	3	3	3	2	3	3	3	20
9.	2	2	2	2	2	2	2	14
average score	1,625	1,714	2,000	1,250	1,625	2,000	2,125	12,34
average difference from the average score	0,719	0,612	0,571	0,375	0,875	0,286	0,438	
maximal score	3	3	3	2	3	3	3	
minimal score	0	1	1	1	0	1	1	
maximal difference between experts' scores	3	2	2	1	3	2	2	

Q24	Study the	propensity o	f the various	vaccines typ	es to lead to	appearance	of escape n	nutants.
Expert	1. Answerability	2. Effectiveness	3. Deliverability	4. Equity	5. Generalization	6. Territory	7. Accessibility	Unweighted sum
1.	3	3	3	1	3	2	2	17
2.	0	2	2	1	1	1		8,16 (!6)
3.	2	2	2	1	1	2	2	12
4.	1	2	2	0	0	2	3	10
5.	3	3	2					18,66 (13)
6.	1	1	1	1	1	1	1	7
7.	2	2	2	1	2	2	2	13
8.	3	3	3		2	3	3	19,83 (16)
9.	1	1	1	1	1	1	1	7
average score	1,778	2,111	2,000	0,857	1,375	1,750	2,000	11,87
average difference from the average score	0,914	0,593	0,444	0,245	0,719	0,563	0,571	
maximal score	3	3	3	1	3	3	3	
minimal score	0	1	1	0	0	1	1	
maximal difference between experts' scores	3	2	2	1	3	2	2	









# Potential mechanisms to increase collaboration in vaccine and vaccination research and cooperation for funding these programmes among MS (WP7.2)

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## List of abbreviations

AMC	Advance Market Commitment
ΑΡΑ	Advance Purchase Agreements
BELSPO-Belgium	BELSPO – Belgian Science Policy Office
CEPI	Coalition for Epidemic Preparedness Innovation
COVAX	Vaccines pillar of the Access to Covid-19 Tools Accelerator
DG	Directorate-General
DLR-PT-Germany	DLR-PT, Federal Ministry of Education and Research, Germany
EC	European Commission
EDCTP	European and Developing Countries Clinical Trials Partnership
ERA	European Research Area
ERC-Estonia	Estonian Research Council, Estonia
ESI	Emergency Support Instrument
EU-JAV	European Joint Action on Vaccination
EWI-Belgium	Governmental Department of Economy, Science and Innovation, Belgium
GAVI	Global Vaccine Alliance
IMI	Innovative Medicines Initiative
JPI	Joint Programming Initiative
JPIAMR	Joint Programming Initiative on Antimicrobial Resistance
MRC-UK	Medical Research Council (UK)
MS	Member State
MoSA-Estonia	Ministry of Social Affairs, Estonia
MoESS-Slovenia	Ministry of Education, Science and Sport, Slovenia
MoHER-France	Ministry of Higher Education and Research, France
NCRD-Poland	National Centre for Research and Development, Poland
NSC-Poland	National Science Centre, Poland
UoM-Malta	University of Malta
Vinnova-Sweden	Vinnova – Sweden's Innovation Agency
WHO	World Health Organisation





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## 1. Introduction

The EU-JAV aims to strengthen cooperation between European countries to fight vaccine preventable diseases. EU-JAV focuses on sharing best practices on national immunisation policies, delivering, and sharing concrete tools for stronger national response to vaccination challenges (1). As such, it will contribute to the implementation of the European Council recommendations on vaccine-preventable diseases (2).

One of the activities of the joint action is related to identifying mechanisms to define tools and methods for priority setting, to increase collaboration in vaccine and vaccination research and cooperation for funding these programmes among European member states. The specific purpose of task 7.2 is to identify sustainable mechanisms to decrease funding fragmentation and increase the potential more collaboration and shared funding on common priorities.

To better understand priorities and financing mechanism at the beginning of the EU-JAV a survey was developed and directed towards organisations funding research and development (R&D) on vaccines and vaccination research. The aim was also to understand the stakeholders and the organisations opinions on mechanisms to fund and collaborate on shared funding for common priorities. Additionally, we asked about their opinion on joint mechanisms for funding of research in vaccination. The survey was launched during 2019 and submitted to a selection of organisations among member states. The results were gathered in 2019. To further gain insight in this area a review of existing and possible funding mechanisms for vaccine research and development was carried out among selected European organisation known to be active in the field of funding for vaccination.

However, in January 2020, the COVID-19 pandemic forced the WP7.2 task leader and the Norwegian Public Health Institute in Norway to focus on handling the national covid-19 pandemic and contributing to their national COVID-19 vaccination programme. The report on the work have therefore been delayed. This delay in the project has also given the opportunity to include some knowledge on the funding mechanisms for COVID-19 vaccines into this report.

## 2. Background and overview of the mapping

The report aims to support ongoing discussions in the EU on joint funding mechanisms and collaboration in this area.

Vaccines have contributed enormously to the successful control and elimination of many diseases. However, the funding of research and development is not evenly distributed along the value chain from basic research through pre-clinical and clinical development, epidemiological





studies, and implementation of vaccines in public health programmes. In addition, the European research landscape is complex. Both the EU and the individual countries fund vaccine research. For vaccines with a clear market potential, the development costs are most frequently funded by large businesses such as the pharmaceutical industry. More early-stage research, basic science and late-stage implementation research often utilise other sources of funding, mostly provided by the public sector. In these areas research councils, charities, philanthropic organisations, and private funders participate and contribute to the funding landscape.

A specific example of lack of funding has been funding of research and development of vaccines for the prevention and control of emerging infectious diseases, such as the diseases included in the World Health organisation (WHO) R&D Blueprint list such as Lassa Fever, Rift Valley fever and Middle East Respiratory syndrome. In this area there has been an urgent need for accelerated research and development, considering the potential for these diseases to cause a public health emergency, and given the absence of efficacious drugs and/or vaccines. The international community – public and private sector alike - therefore decided to come together to establish and fund the Coalition for Epidemic Preparedness Innovation (CEPI), a new global partnership for funding vaccine R&D (3).

The COVID-19 pandemic has urgently forced the national funding authorities as well as the EU MS to rapidly act to fund development of COVID-19 vaccines. Besides, research and clinical development, massive funding of the production and manufacturing of COVID-19 vaccines has also taken place to ensure supply of the vaccines. Some of the publicly available information on these mechanisms have therefore been included and discussed in the report.

### 3. Methodology

A literature review of existing and possible funding mechanisms for vaccine research and development was carried out in 2019 to gain an overview of organisations providing funding of vaccine R&D and vaccination research. The methodology was discussed and validated by the partners of the EU-JAV. Additionally, to better understand priorities and financing mechanisms, a survey was developed and directed towards organisations funding research and development (R&D) on vaccines and vaccination research (Annex I). The aim was to understand the stakeholders and the organisations opinions on mechanisms to fund and collaborate on shared funding for common priorities. The survey was shared with the EU-JAV partners for review and comments.

Based on the EU-JAV partner's feedback, comments, and internal discussions as well as information from the overall mapping exercise, the survey towards organizations funding research was carried out during spring 2019. An invitation to participate in a Quest back webbased survey was submitted via email correspondence to relevant organisations. The aim was to use the combined findings from the survey and the literature review of existing funding mechanism to propose a potential mechanism to increase collaboration in vaccine and vaccination research and cooperation for funding of identified priorities in task 7.1.

Our analysis additionally draws on earlier work identified in the literature review as papers, meeting reports, publicly available policy documents, minutes from meetings of governing





bodies, as well as published comments by stakeholders. Knowledge on the funding mechanisms for covid-19 vaccine and the mechanisms into this report are gained from literature search of publicly available information.

**Ethics:** In addition to the survey, all persons invited to participate were sent a privacy statement according to GDPR 2018.

4. Results

## VII- <u>4.1 Participating organisations to the Survey</u>

The survey was launched in March 2019 and submitted to 34 relevant organisations. The organisations were selected based on the results of the mapping of funders and feedback obtained from Director General (DG) Research and Innovation at the European Commission (EC). Fourteen organisations responded to the survey, see table 1. The questionnaire consisted of three different sections. The survey was built into a Quest back web-based survey and submitted via email correspondence to relevant respondents.

Organisation	Full name, Geographical Area
EDCTP	European and Developing Countries Clinical Trials Partnership, EU
EWI-Belgium	Governmental Department of Economy, Science and Innovation, Belgium
MRC-UK	Medical Research Council, UK
UoM-Malta	University of Malta, Malta
Vinnova-Sweden	Vinnova – Sweden's Innovation Agency, Sweden
BELSPO-Belgium	Belgian Science Policy Office, Belgium
ERC-Estonia	Estonian Research Council, Estonia
MoSA-Estonia	Ministry of Social Affairs, Estonia
MoESS-Slovenia	Ministry of Education, Science and Sport, Slovenia
NCRD-Poland	National Centre for Research and Development, Poland
EC	European Commission, EU
MoHER-France	Ministry of Higher Education and Research, France
NSC-Poland	National Science Centre, Poland

Table. 1. Organisations that responded to the survey





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DLR-PT-Germany
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DLR-PT, Federal Ministry of Education and Research, Germany

## VIII- <u>4.2 Overview of other relevant organisations funding vaccine</u> research and research in vaccination

The literature review of existing and possible funding mechanisms for vaccine research and development was carried out among selected European and international organisation operating in the EU known to be active in the field of funding for vaccination. Most of these organisations are not funded directly by the member states but have a combination of different financing mechanisms. Very few of these organisations responded to our request to answer the survey mentioned in section 4.1.

Table 2. Selected organisations and key information on funding and mechanisms for organisations not responding to the survey, known to be active in the field of funding vaccine R&D and/or vaccination research

Organisation	Short Description	Type of funding mechanism
Innovative Medicines Initiative (IMI) (4)	Public-private partnership (PPP) in the life sciences	Partnership between the EU (represented by the EC) and the European pharmaceutical industry (represented the European Federation of Pharmaceutical Industries and Associations (EFPIA)).
Wellcome (5)	A global UK based charitable foundation, politically and financially independent	Global Alliance for Vaccines and Immunization (Gavi)Scholarships, Awards, Fellowships, Collaborative awards, Studentships, Epidemic preparedness, PhD programmes, Human Infection Studies for Vaccine Development, Joint Global Health Trial schemes, Joint Health systems research schemes
Bill & Melinda Gates Foundation (BMGF) (6)	A US-based private foundation, global scope	
UK Vaccine Network (7)	The network brings together industry, academia and relevant funding bodies to make targeted investments in specific vaccines and vaccine technology for infectious diseases with the potential to cause an epidemic	
СЕРІ (3)	An alliance with the aim to finance and coordinate the development of novel vaccines to prevent and contain epidemics due to emerging or re-emerging infectious diseases. The main investors at the beginning were the government of Norway, the government of Japan, The federal government of Germany, BMGF, Wellcome, EC, the government of Belgium, the Government of Canada, the Government of Australia. The main investors today consist of about 30 countries BMGF, Wellcome, EC and USAID.	Funding through selected - calls for proposals





Joint Programming Initiative (JPI) Mechanism (8)	The Joint Programming Initiative on Antimicrobial Resistance (JPIAMR) was formed 2011 by 15 European countries with the support of the EC	Funds basic and exploratory research on new antibiotics, stewardship of existing antibiotics, and studies and control of the spread of antibiotic resistance between humans, animals, and the environment in a One Health perspective. Supports research through several activities such as the establishment of a Virtual Research Institute. JPIAMR coordinate national research programmes on AMR through its Strategic Research Agenda and with input from the IMI and a network of non- governmental stakeholders
Global Alliance for Vaccines and Immunization (GAVI) (9)	Public-private partnership. Gavi was created to bring together key UN agencies, governments, the vaccine industry, private sector, and civil society to improve childhood immunization coverage in poor countries and to accelerate access to new vaccines. The model was designed to leverage not just financial resources but expertise to help make vaccines more affordable, more available and their provision more sustainable.	

## IX- <u>4.3 Results of the survey</u>

### 3) <u>4.3.1 Areas and types of research for which responding organisations</u> provide funding

The respondents of the survey were asked which areas of research they provided funding for (table 3). Most of the organisations provided funding for all scientific disciplines, not only health or health related topics. Other areas mentioned were infra structure and educational activities. Table 3. Areas of research for which responding organisations provide funding (N=14).

Which research areas does you organization provide funding for?	Number of respondents
All scientific disciplines	11
Others, e.g., infrastructure, educational activities	5
Only specific disciplines	3

A few of the organisations gave more details on funding of specific scientific disciplines and the responses and they are listed in table 4.

#### Table 4. More detailed information on specific funding areas

Organisation	Only specific scientific disciplines (please specify)	Others, e.g., infrastructure, educational activities (please specify):
EDCTP	Clinical trials in sub-Saharan Africa for new medicinal products against poverty-related infectious diseases	Capacity building (networking and individual fellowships) for clinical research in sub-Saharan Africa
EWI-Belgium	-	European Strategy Forum on Research Infrastructures (ESFRI)





	agenda, Big equipment, co-fin bio incubators		
MRC-UK	Medical research	Infrastructure, educational activities, public engagement, workshops, conferences.	
MoSA-Estonia	Health research, social sciences	Specific educational activities in health and social welfare	
MoHER-France	-	Infrastructure, higher education, research organisms, universities, regulatory agencies	
DLR-PT-Germany	-	e.g., medical/scientific training, biobanks, registries	

The respondents were asked about key types of research and development they funded (table 5) as well as presence or absence of funding of vaccine research and development (R&D) or vaccination research (figure1). In this context vaccine R&D is vaccine product development, while vaccination research is basic research including epidemiological studies etc. The results in table 5 list by the respondents the key areas for funding. Basic research, implementation, social science and pre-clinical development in the area General R&D and basic research and pre-clinical development followed by implementation and clinical development in the area Vaccine R&D. More than half of the organisations responded that they funded vaccine R&D and vaccination research as a part of their portfolio. Some of the organisations provided some additional comments on the amount of total funding in these areas, however these figures were quite variable in terms of content and quality, see the responses presented in table 6.

Table 5. Types of research and development the organisation provide funding for

Which types of research and development does you organisation provide funding for? N= 14		
Types of research	General	Vaccine
	Research	Research and
	and	Development
	Development	
Basic research	10	9
Implementation	10	7
Social sciences	9	4
Pre-clinical development	9	8
Clinical development	8	7
Epidemiological studies	8	6
Discovery	7	7
Phase IV and pharmacovigilance studies	3	2
Others	1	0





responding	or	ganisation	(N=14)
8	9	6	4
Yes, vaccine R&D (product R&D)	Yes, research on vaccination	No, vaccine R&D (product R&D)	No, research on vaccination

## Figure 1. Presence or absence of funding of vaccine research and development (product R&D) at the

### Table 6. Additional feedback on the amount of total funding research and development in these areas

Organisation		
	How much is your total funding of research and development?	
EDCTP	Approximately 800 million Euro for the period between 2014-2024 (683 million from the EU + approximately 120 million from partner countries and third parties)	
EWI-Belgium	STI budget: 2. 858 billion Euro, of which 1. 6 billion Euro R&D in 2018	
MRC-UK	814 million pound per annum	
Vinnova-Sweden	Funding in total 80 million Euro in the health area, not specific funding for vaccines	
ERC-Estonia	304 million Euro in 2017	
MoSA-Estonia	Funding varies yearly	
NCRD-Poland	Around 4 billion Euro	
EC	The total budget for the current research and innovation programme H2020 is 77 billion Euro. There is no budget earmarked for vaccine research	





MoHER-France	Overall, the national French budget for research is around 11.5 billion Euro, the program 172 Multidisciplinary scientific and technological research is 6.8 billion Euro
NSC-Poland	NCN only funds basic research (not R&D); the total funding in 2011-2018 for basic research was 7.88 billion PLN (national + international calls); earmarked subsidy for 2019, 1.2 billion PLN (the same for 2018)
DLR-PT-Germany	Overall budget of BMBF 18 Billion Euro in 2019
	Please specify a yearly amount for vaccine research and development
EDCTP	Approximately 100 million Euro, 30 % for vaccines
EWI-Belgium	1.6 billion Euro
MRC-UK	approximately 814 million pounds, 2 % for vaccines
UoM-Malta	There is no dedicated amount to vaccine research
ERC-Estonia	125,3 million Euro from the public sector (mainly Estonian Research Council, some part comes directly form Ministries)
MoSA-Estonia	7 million Euro in 2018
MoESS-Slovenia	Annual amount varies. Figures for 2018: 2 million Euro for international collaboration (research projects and European research infrastructure)
NCRD-Poland	around 1 billion Euro
EC	In H2020 (2014-2018) so far for vaccine and vaccination R&D, 490 million Euro have been committed
MoHER-France	Among the program 172, the amount dedicated to the Agence Nationale de Recherche for the generic open call is around 420-450 million Euro. There is no specific identification or isolation of vaccine projects. Projects can be funded through various committees; however, the Immunology, Infectiology, and Inflammation Committee has a budget around 12 million Euro.
	Place specify a percentage and yearly amount for vascination
	research
MRC-UK	Currently 55 million pound per annum (6%)
UoM-Malta	Only if this is a successful project application - none ongoing at present
ERC-Estonia	There is no specific programme for funding research on vaccination. We
	use bottom-up approach in national funding (no prescribed topics), then
	any excellent proposal, including those about vaccination, may get
	funded
MoSA-Estonia	Funding is project-based and varies yearly; yearly studies on vaccination
	coverage is performed by Estonian Health Board using internal resources
EC	So far in H2020, 490 million Euro have been committed to vaccine or vaccination R&D
MoHER-France	Continuing the above comments: vaccine and vaccination research are not identified separately. There are also other portals for funding other than ANR.

The respondents were asked if they funded specific prioritised areas for research and development of vaccine and vaccination research. The results are presented in figure 2. Two of the organisations provided some more specific comments and these are listed in table 7.







### Figure 2. Types of prioritised areas of funding for vaccine and vaccination research (N=14)

## Table 7. Comments to specific priority areas for funding from EDCTP and DLR-PT-GermanyOrganisationOnly specific disease areas (please specify):

EDCTP	Poverty-related infectious diseases: HIV, tuberculosis, malaria, neglected
	infectious diseases, diarrhoeal and lower respiratory infections, and
	emerging infectious diseases
DLR-PT-Germany	diarrhoeal diseases or lower respiratory tract infections
	Comments to the topic emerging diseases as a specific prioritised area:
EDCTP	Emerging infectious diseases of relevance for sub-Saharan Africa, for example Ebola, Lassa, and yellow fever
DLR-PT-Germany	They fund platform technologies for emerging diseases.
	Comments to the topic neglected diseases as a specific prioritised area:
DLR-PT-Germany	They fund Malaria, HIV, TB
	Comments to the topic pandemic threats as a specific prioritised area:





DLR-PT-Germany

They fund Nipah, Lassa, MERS, Ebola, RVF, Chikungunya

The respondents were asked if they funded some selected specific four disease areas of research and development for vaccine and vaccination research. These areas were specifically selected based on the disease priorities selected in the WP7 Task 1 of the EU-JAV. The selected disease areas were: Influenza virus, pandemic influenza virus, Human papilloma virus, measles, mumps or rubella virus and pertussis bacteria. The results are presented in table 8 below.

Table 8. Selected areas for vaccine research and development or vaccination research (N=14)

Has your organisation funded vaccine research and development or vaccination research the last two years in the selected disease areas?	Number of respondents		
Types of research	Research and Development	Vaccination Research	
Influenza virus	4		4
Pandemic influenza virus	3		2
Human papilloma virus	5		4
Measles, mumps, or rubella virus	0		0
Pertussis bacteria	1		1

# 4) <u>4.3.2 Funding mechanisms used, collaboration on funding and governance</u>

The respondents were asked to give information on the different mechanisms they used to fund research. The responses are listed in table 9. The key mechanisms they listed for funding were i) calls for grant applications ii) joint calls with other funders and iii) infrastructure support. Some of the organisations provided some additional examples of collaboration with funders to the mechanisms as presented in table 10. Many of the organisations reported experiences with collaborating with other funders, and 8 of the organisations reported a need to collaborate with other funders in vaccine research. Examples and more detailed descriptions are presented in table 14 and 15, below.

### Table 9. Mechanisms used by responding organisations to fund research.

Which mechanisms does your organisation use to fund research?	N= 14
Calls for grant applications	12
Joint calls with other funders	11
Infrastructure support	10
Collaboration with other funders	8
Others	5
Open applications	3

### Table 10. Additional comments to funding mechanism





Organisation	Examples of collaboration with other funders
EWI-Belgium	EWI is the overarching ministry that supports the funding agencies FWO and VLAIO
MRC-UK	Wellcome, UK Government departments, Charitable partners
Vinnova-Sweden	Swedish research council
NCRD-Poland	Bilateral cooperation
EC	Collaboration (partnerships (IMI, EDCTP); policy; joint calls). Main partners: Member states, associated countries, third countries, BMGF and other foundations, CEPI, pharma industry
MoHER-France	Most calls for projects and grants go through the Agency National de la Recherche, ANR. We interact with other nations, other ministries, funding agencies steered by other ministries, etc.
NSC-Poland	Bilateral and multilateral cooperation with research funding organisations from other countries within different frameworks
DLR-PT-Germany	e.g., CEPI, EDCTP, Grand Challenges Africa
	laint Calls with other funders
FUCTE	We collaborate with other organisations to establish a common not that is
LDCIF	used for open calls around a jointly defined research theme
EWI-Belaium	In some cases, we collaborate with FWO and VLAIO
MRC-UK	Wellcome, UK Government departments, Charitable partners
ERC-Estonia	H2020 ERA-Nets
MoESS-Slovenia	Participation in joint transnational calls via ERA-NET Co-funds
NCRD-Poland	ERA-NET programmes, JPI programmes, EJP programmes etc.
EC	We organise ad-hoc joint calls for proposals with other funders, which are published in our H2020 annual work programmes.
MoHER-France	Same as above
NSC-Poland	Joint calls within bilateral programmes (for example with Germany, Lithuania, China, Austria); joint calls within ERA-NET Co-funds and multilateral initiatives (for example CHIST-ERA, QuantERA, Solar-Driven Chemistry, JPcofund 2)
DLR-PT-Germany	e.g. JPIAMR, ERA-Nets
	Open applications
EWI-Belgium	Sometimes stakeholders bring important issues to our attention and ask for funding
EIA// De leisure	Others
EWI-Belgium	We also identify important needs and can then provide funding
IVIOSA-Estonia	Public tenders to carry out R&D activities
WOESS-Slovenia	Slovenian Research Agency, which holds national calls for research projects and programmes in all scientific disciplines
NCRD-Poland	venture capital, hub projects
EC	innovation prizes





The respondents were asked to give information on the governance mechanisms involved in the development and decisions on their calls for proposals. The responses and comments are presented in table 11 and 12.

Table.11 Governance structures involved in the development and decision making of calls for proposals or funding opportunities

Types of governance structures involved in the development and decision making of calls for proposals or funding opportunities	N= 14	
Types of research	Development of calls for proposals	Decision making on calls for proposals
The Board	5	7
Investment committee	0	0
Scientific advisory committee	7	4
External experts	7	6
Internal experts in our organisation	6	6
Others	4	4

## Table.12 Comments to the governance structures involved in the development and decision making of calls for proposals or funding opportunities

	Development of calls for proposals
EWI-Belgium	We do not have specific calls, only bottom-up proposals on any topic. The criteria for selection are excellence; selection is done by external experts, including international experts
MoESS-Slovenia	No governance structure is involved in development of calls at the ministry. Slovenian Research Agency receives funding from the ministry, and they develop calls for proposals.
EC	The Commission develops and drafts calls/funding opportunities (considering inputs for scientific advisory board) which are discussed/revised/agreed with Programme Committees (Member States and Associated Countries representatives
MoHER-France	The MESRI preferentially operates calls through a dedicated funding agency, ANR. Other funding agencies can also operate, and other ministries

	Decision making of calls for proposals
MoESS-Slovenia	Internal Committee/Working group
NCRD-Poland	Director decision
EC	Independent external experts assist the Commission for the evaluation of the proposals. The Commission, and the programme committee of MS/AC, are involved in decision making process.
MoHER-France	ANR and other funding agencies





#### Table 13. Types of eligibility criteria used for funding opportunities.

Types of eligibility criteria used for funding opportunities.	N= 14
Applicant specific criteria	7
Consortiums must be formed	7
In kind contribution	4
Public private collaboration	3
Co-funding requirements	3
Other collaborative measures	1
Others	5

### Additional explanation/other collaborative requirements reported were

Other eligibility criteria mentioned were: i) the need to form consortia, ii) there must be at least 3 members from different member states iii) eligibility could depend on the stage of the academic career of the principal investigator as well as the need for the project leader or the institution where the project is held must be from a specific geographic location. Additionally, a few mentioned eligibility criteria such as: sufficient experiences and ability to carry out the project, scientific excellence, feasibility, innovation, medical need, relevance to the calls.

Many of the organisations reported experiences with collaborating with other funders, and 8 of the 14 organisations reported a need to collaborate with other funders in vaccine research. Examples and more detailed descriptions are presented in table 14 and 15, below.

Organisation	Description of and type of collaboration with other funders
EDCTP	Joint calls: where each funder provides a cash contribution, and a joint call text is developed and joint selection procedure for applications.
MRC-UK	Co-funding with other research councils in the UK (for example BBSRC) We also co-fund with the Department of Health and Social Care the UK Vaccine Network (£120million over five years, which looks at developing vaccines against emerging infectious diseases)
Vinnova-Sweden	Joint call within the health area
ERC-Estonia	EU research partnerships like ERA-Nets, JPIs, some research infrastructure programmes.
MoSA-Estonia	Co-funding of research projects, e.g., with local research council.
MoESS-Slovenia	ERA-NET Co-founds and JPIs.
NCRD-Poland	Bilateral cooperation, ERA-NET scheme, JPI scheme, collaboration with the industry (domestic programmes)

Table 14.	Examples and	description of e	xperience with a	collaborating with	other funders.
	Examples and	acouption of c	Aperience with the		i other runders.





EC	Creation of partnerships, e.g.: public-public partnership (EDCTP. EC and participating member states) public-private partnership (IMI. EC and EFPIA) collaboration and funding to CEPI collaboration in GloPID-R (alliance of global funding bodies (including EC) investing in research related to new or re-emerging infectious diseases) collaboration with other funders for adhoc calls for R&D	
MoHER-France	multinational call between different national agencies or ministries, European Commission tools such as era nets, JPIs, EJPs	
NSC-Poland	Bilateral and multilateral cooperation with Research Funding Organisations from different countries within different frameworks, ex. ERA-NET Co-fund programmes	
DLR-PT-Germany	CEPI, JPIAMR, EDCTP - Joint funding of vaccine development	

Table 15. Examples and description of need to collaborate with other funders in vaccine res	search.
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Organisation	Examples and description of need to collaborate with other funders in vaccine research	
EDCTP	Late-stage clinical trials for vaccines can be so large and expensive that it is difficult for a single funder to cover the entire costs	
MRC-UK	To deliver larger projects, but also to collaborate with industry - it is important that any projects funded through public money have a chance to be developed into a usable vaccine.	
UoM-Malta	It does not make sense for each country to conduct its own research in this field. Research must however be locally implemented too as it must be contextualised within the culture and health system when it comes to epidemiology and implementation research.	
ERC-Estonia	European partnerships under umbrella of Framework Programme	
MoSA-Estonia	Co-funding schemes with other ministries.	
EC	The development of novel vaccines and optimization of existing ones is a very complex and risky research field, which requires high investments and collaboration between parties having different expertise.	
MoHER-France	Very active scientific field. Application of recent research data on immunology, need for safer vaccine / adjuvants, understand, and react to vaccine hesitancy, need to develop One Health approach to emerging threats, possible major progress in the field of respiratory infections, potential for a whole set of innovation in vaccination for non-infectious diseases: some rare diseases, immune-related diseases (auto-immunity), some metabolic diseases.	
DLR-PT-Germany	Too expensive for one funder alone; Need for specific competences in different countries; broaden target population;	

## The respondents were asked about what they considered to be the most important factors needed for collaboration with other funders. The results are presented in the figure 3 below.







### Figure 3. Most important factors needed for collaboration with other funders (N=14)

Additionally, some of the respondents gave additional comments on factors needed for collaboration with other funders. Core protocol for all and adapted protocols per country, Sufficient funds and high national research interest in the topic and the need for alignment of national scientific communities

### 5) <u>4.3.3 Would a potential future joint European mechanism increase</u> collaborative efforts in vaccine R&D and vaccination research

Participants were asked if they believed a potential future joint European mechanism (i.e., a JPI) would increase collaborative efforts in vaccine R&D and vaccination research. Six of the 14 organisations responded "yes" to the question, six were unsure, one organisation responded no, and one did not respond. Additionally, they were asked to comment on their view on best ways to develop collaboration funding mechanism in EU and specific priority areas for a future JPI in vaccine R&D and vaccination research. The feedback and comments are presented in the table 17 and 18 below.

### Table 17. Respondent's opinion on best ways to develop collaboration funding mechanism in EU





Organisation	Best ways to develop collaboration funding mechanism in EU		
EDCTP	A new Joint Programming Initiative (JPI), Preferably a JPI with a sizeable common pot of funding to allow implementation of activities		
MRC-UK	A new Joint Programming Initiative (JPI)		
UoM-Malta	A new Joint Programming Initiative (JPI)		
Vinnova-Sweden	A new Joint Programming Initiative (JPI)		
ERC-Estonia	A new Joint Programming Initiative (JPI)		
MoSA-Estonia	Member states and EU could support research on vaccination coverage, safety, effectiveness and demand of vaccines. This could be supported by voluntary cooperation between countries aided by EC		
MoESS-Slovenia	Others, Co-fund mechanisms		
EC	Voluntary collaboration between funding agencies		
MoHER-France	Support and aided by draft agreements made by the EC		
NSC-Poland	Voluntary collaboration between funding agencies		
Table 19. Specific priority areas of a future IPI in vaccine P&D and vaccination research			

 I able 18. Specific priority areas of a future JPI in vaccine R&D and vaccination research

 Specific priority areas of a future JPI in vaccine R&D and vaccination research.

 Number of res

Number of respondents (N)

Emerging infectious diseases	4
Pandemic vaccines/Vaccines to be used during epidemic outbreaks	4
Vaccines where more data on safety and follow-up is needed e.g., HPV	2
Vaccines with low effectiveness, e.g., influenza	2
Vaccines against diseases causing frequent outbreaks today, e-g- measles	1
Specific vaccines in the immunisation schedule	1
Rarely used vaccines and immunoglobulins	0
Vaccines with low efficacy. E.g., pertussis bacteria	0
Others	3

Only four respondents wanted to prioritise vaccines for emerging infectious diseases, pandemic vaccines, and vaccines to be used during epidemic outbreaks. Additionally, some responded specific vaccines in the immunisation schedule were more data on safety and follow-up is needed and influenza due to low effectiveness.

Other comments were that collaboration in funding research could be useful for vaccines with little or no commercial interest, where private investments are too low, vaccines as a tool to combat AMR, but also to fund social science and behaviour science, health economy and reimbursement models.

Comments from the respondents who did not see the need for a new collaborative mechanism were that the member state co-funded EU mechanism does not have to support product R&D. There are already several European and international mechanisms in place to support vaccine and vaccination R&D and they were unsure whether a novel mechanism is needed and would increase collaborative efforts in this area.

One additional comment was given on the need for improvement of prevention of primary herpes infections, since there are no vaccines to prevent this infection and treatment strategies are limited to the antiviral agents blocking viral replication.





## X- <u>4.4 Description of other funding mechanism - selected</u> organisations active in financing vaccine research and research in vaccination

To further gain insight in this area of other organisations and funding mechanisms, a review of the websites and some key reports of existing and possible funding mechanisms for vaccine research and development was carried out among selected European organisations known to be active in the field of funding for vaccination. A short summary of the focus areas in the vaccine field for the different organisations are presented below. Most of these organisations are not funded directly by the European member states but are financed through a combination of different mechanisms and country support. Very few of these organisations responded to our request to answer the survey described in section 4.1, but most of these organisations have publicly available information on their overall scope, governance, and funding areas.

### 6) <u>4.4.1 Wellcome</u>

Wellcome is a global UK based charitable foundation, which is politically and financially independent. The Wellcome Trust directly fund thousands of scientists and researchers around the world from discovery to impact. Their funding schemes offer grants across biomedical science, population health, medical innovation, humanities and social science, and public engagement. The Trust is governed by its Constitution, and the Board of Governors guides and oversees that Wellcome is achieving its mission to improve health for everyone by helping great ideas thrive (5).

**Funding within the field of vaccines:** Wellcome state on their homepage that "one of the key areas of funding within the field of vaccines are the development of new and improved vaccines as well as enabling better and broader use of the already existing vaccines". Examples of funding initiatives for vaccines are:

- The joint effort aimed at developing a universal influenza vaccine
- Forming an evidence-base for reducing the dose of the yellow fever vaccine
- Funding a joint initiative on epidemics preparedness
- Funding of CEPI; and supporting WHO in creating a R&D blueprint for tackling Lassa fever, Nipah and Ebola
- COVID-19 vaccines

Wellcome is funded from an investment portfolio. The original source of funds was donated by Sir Henry Wellcome in 1936, and currently the funding comes from a wide range of financial assets around the world. The Trust does not generally receive donations or government grants.

### 7) <u>4.4.2 The Bill and Melinda Gates Foundation</u>

The Bill and Melinda Gates Foundation aims to help all people lead healthy, productive lives. In global health, the Foundation focuses on, amongst others accelerating the development of new




vaccines for low-resource settings through innovation in technologies, platforms, processes, and business models to reduce costs and time-constraints in this development (6). **Funding within the field of vaccines:** 

# Investments in vaccines for rotavirus and other leading bacterial causes of diarrheal and enteric

- diseases such as cholera and typhoid are key areas of efforts, including investing in the development of a vaccine against *Shigella*
- Another top priority is to promote full-scale delivery of currently available pneumococcal and meningococcal vaccines and to support the development of new vaccines to improve coverage, efficacy, safety, and cost-effectiveness
- Contributing to the global polio eradication initiative is another important area of focus as well as contributing to deliver high, equitable and sustainable vaccine coverage globally
- COVID-19 vaccines

Bill & Melinda Gates Foundation state on their homepage. "In 2006 the Bill & Melinda Gates Foundation (foundation) and the Bill & Melinda Gates Foundation Trust (trust). Both entities are tax-exempt private foundations that are structured as a charitable trust. The Foundation works to achieve its mission goals, whilst the Trust holds and manages the donated investment assets. Their key strategy is to invest in expertise and platform technologies that help us make vaccines faster, better, and cheaper. They also invest in education and training to ensure that knowledge around vaccine development and manufacturing is created, shared, and retained". Some examples of this include:

- adaptive trial design.
- streamlining the schedule and dosing of vaccines
- novel delivery formats for vaccines; and
- modular, automated manufacturing platforms enabling small-batch vaccine production.

BMGF lists selected partners in this area of funding and collaboration: Child Health and Mortality Prevention Surveillance (CHAMPS), Countrywide Mortality Surveillance for Action (COMSA), The Institute for Health Metrics and Evaluation (IHME) and Coalition for Epidemic Preparedness Innovations (CEPI).

## 8) <u>4.4.3. Global Alliance for Vaccines and Immunization (Gavi)</u>

Global Alliance for Vaccines and Immunization (Gavi) is a public-private partnership. Gavi was created to bring together key UN agencies, governments, the vaccine industry, private sector, and civil society to improve childhood immunization coverage in poor countries and to accelerate access to new vaccines. The model was designed to leverage not just financial resources but expertise to help make vaccines more affordable, more available and their provision more sustainable, by working towards a point where developing countries can pay for them themselves (9).

### Funding within the field of vaccines:

• Leverage not just financial resources but expertise too, to help make vaccines more affordable, more available and their provision more sustainable





- The Advance Market Commitment (AMC) innovative funding mechanism incentivises vaccine makers to produce vaccines for the world's poorest countries
- In 2014, the Board approved a funding envelope which includes about \$300 million earmarked for the procurement through UNICEF of licensed, prequalified Ebola vaccines and the establishment of a stockpile for 2016-2020
- Covid-19 vaccines

Gavi state on their homepage: Gavi relies on country-based systems and works with partners with widespread field presence to deliver its programmes. Providing a single forum for each partners' unique perspectives has yielded a fertile ground for collaboration and innovation. Partners contribute to the Vaccine Alliance through participation in strategy and policy-setting, advocacy, fundraising, vaccine development and procurement, country support and immunisation delivery. While the Gavi Secretariat oversees the day-to-day operations of the Vaccine Alliance, the Board is responsible for giving strategic direction and policymaking. The Gavi Board is responsible for strategic direction and policymaking, oversees the operations of the Vaccine Alliance and monitors programme implementation.

The AMC is designed to protect children and save lives. Through donor commitments, this innovative funding mechanism incentivises vaccine makers to produce vaccines for the world's poorest countries. These countries are then able to plan for immunization programs knowing that vaccines will be available rapidly, in the quantities they need and at affordable prices. The AMC aims to address this challenge by stimulating the late-stage development and manufacture of suitable vaccines at affordable prices. Through an AMC, donors commit money to guarantee the price of vaccines once they have been developed, thus creating the potential for a viable future market. These commitments provide vaccine makers with the incentive to invest the considerable sums required to conduct research and development and build manufacturing capacity. Companies that participate in the AMC will make legally binding long-term commitments to supply the vaccines at lower and sustainable prices after the donor funds are spent. Implementing countries will provide a small co-payment to contribute towards the cost of the vaccines.

In 2015, Gavi offered an Advanced Purchase Commitment (APC) to several manufacturers of candidate Ebola vaccines and in late 2015 the Gavi Executive Committee approved an APC, including a prepayment of \$5 million to Merck. The value of the prepayment will be used as a credit against the first procurement of licensed vaccine for a stockpile. A requirement of the APC is that a quantity of investigational vaccine be made available for outbreak response under guidance from WHO. A principle across all vaccine investments is that Gavi only supports the procurement of licenced, WHO prequalified vaccines. The Vaccine Investment Strategy (VIS) for 2019-2024 will review the feasibility and desirability of extending Gavi support for the funding of a licenced second-generation vaccine with enhanced properties or stockpile use.

### 9) <u>4.4.4 UK Vaccine Network</u>

The UK Vaccine Network brings together industry, academia, and relevant funding bodies to make targeted investments in specific vaccines and vaccine technology for infectious diseases with the potential to cause an epidemic. The UK government is taking concerted and coordinated

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action to address the lack of funding of research and development of vaccines for the prevention and control of emerging infectious diseases (7).

### Funding within the field of vaccines:

- Investments of £120 million between 2016 and 2021 for the development of new vaccines for infectious diseases with the potential to cause an epidemic, in line with the expert advice provided by the UK Vaccines Network.
- The network provided funding to support Oxford University to develop a vaccine for Middle East Respiratory Syndrome (MERS). This vaccine technology was rapidly repurposed to develop a COVID-19 vaccine using initial funding from a National Institute for Health Research (NIHR) and UK Research and Innovation (UKRI).

The focus of the Network has been supporting the government to identify and shortlist targeted investment opportunities for the most promising vaccines and vaccine technologies that will help combat infectious diseases with epidemic potential, and to address structural issues related to the UK's broader vaccine infrastructure. The Vaccine Network operates through a series of working groups. Each group has a specific focus, and they feedback their findings to the Network. Working group 1: Identify and prioritise human and zoonotic diseases. Working group 2: Understand how a vaccine will impact on an epidemic disease outbreak. Working group 3: Produce a process map for vaccine development, from discovery to deployment. Working group 4: Look at the manufacture of vaccines.

### 10) <u>4.4.5 Coalition of epidemic preparedness innovation (CEPI)</u>

CEPI is an innovative global partnership between public, private, philanthropic, and civil society organisations. The goal is to accelerate the development of vaccines against emerging infectious diseases and enable equitable access to these vaccines for people during outbreaks (3). The Wellcome Trust, the World Economic Forum, the Government of Norway, the Government of India and the Bill and Melinda Gates Foundation launched CEPI in Davos in January 2017. CEPI is a multi-stakeholder coalition and a legally independent transnational entity that aims to stimulate, finance, and co-ordinate the development of vaccines against potentially epidemic infectious diseases for which the market potential is limited. This was the first global R&D funding mechanism aiming to enhance coordination of the R&D process for developing vaccines for use in outbreak situations. CEPI has secured financial support from Australia, Austria, Belgium, the Bill & Melinda Gates Foundation, Canada, Denmark, the European Commission, Finland, Germany, Hungary, Italy, Japan, Kuwait, Lithuania, Luxembourg, Malaysia, Mexico, Netherlands, New Zealand, Norway, Panama, Saudi Arabia, Serbia, Singapore, Switzerland, United Kingdom, USAID, Ethiopia, The Republic of Korea, Indonesia, and Wellcome among others. Additionally, CEPI has also received support from private sector entities as well as public contributions through the UN Foundation COVID-19 Solidarity Response Fund.

### Funding within the field of vaccines:

Calls for proposals

• Focus on vaccine development from late preclinical development to proof of concept, phase 2 for diseases listed on the WHO R&D Blueprint list. Diseases with emerging infectious disease





potential. Preclinical and clinical development, some support to epidemiological studies for relevant diseases.

- Disease X (represents the knowledge that a serious international pandemic could be caused by a pathogen currently unknown to cause human disease).
- Funding of COVID-19 vaccines

The scientific advisory committee give advice to the Board on their decisions on funding. Requirements are set in the different call for proposals, no specific rules on eligibility, number of partners and how the consortia must collaborate. The proposed budget from the applicants is reviewed and challenges from the CEPI Business Development.

During the COVID-19 pandemic CEPI has taken a more end-to end approach operating both as a funder and a facilitator for licensure and manufacturing. They have been active in the coordination of COVAX together with Gavi and WHO. COVAX, described more separately below, aims to act as a platform to support the research, development, and manufacturing of a wide range of COVID-19 vaccine candidates and negotiate their pricing (10).

### 11) 4.4.6 Innovative Medicines Initiative, IMI

Innovative Medicines Initiative (IMI) is a public-private partnership (PPP) in the life sciences. It is a partnership between the European Union (represented by the European Commission) and the European pharmaceutical industry (represented by EFPIA, the European Federation of Pharmaceutical Industries and Associations). Public private partnership with a multi-annual strategic research agenda. The partnership has a strong focus on priority disease areas, where safe, effective treatments are lacking, and/or where the impact on public health is greatest (4).

### Funding within the field of vaccines:

The PPP has no specific focus in vaccine or vaccination research. Vaccine was back in 2019 one of 12 listed projects. IMI has a high focus on Ebola vaccines and RSV. One project with focus on standardization and development of assays for assessment of influenza vaccines correlates of protection. Some projects they fund within the field of vaccines are: Development of robust and innovative vaccine effectiveness focus on influensa, called DRIVE. Development of pertussis correlates of protection in Europe, called PERISCOPE. Individual EFPIA member companies, an IMI Strategic Governing Group (SGG) or an associated partner or third parties, may submit ideas for topics. Third party ideas can be submitted via the specific form available on their website and can cover the whole value chain of vaccine research and development.

The key areas are i) target validation and biomarker research (efficacy and safety) ii) adoption of innovative clinical trial paradigms and iii) innovative medicines.

The annual work plan of IMI is approved by the governing bodies. Each topic suggested is subject to a formal consultation with the European Commission (EC), the IMI States Representatives Group (SRG) and the IMI Scientific Committee (SC). The final decision on whether a topic will be part of a call is the responsibility of the IMI Governing Board. Following the Governing Board's green light, IMI launches a call for proposals on its website and the EC's Participant Portal. In-kind contribution from EFPIA partners (different percentages of the project amount) are required.

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## 12) 4.4.7 Joint Programming Mechanism, JPI mechanism – example

One example of the mechanism Joint Programming Initiative is the Joint Programming Initiative on Antimicrobial Resistance, JPIAMR. JPIAMR is an international collaborative platform currently engaging 28 nations and the EC as a non-voting member. They work together in the alignment of activities between member countries and the EC framework programme regarding AMR research and funding. The Commission has supported JPIAMR key coordinating operations through several grants, most frequently mechanism is Coordination and Support Actions. The JPI has now specific funding within the field of vaccine but is included in the overview since this was one of the mechanisms included in the survey.

## XI- 4.5 Financing mechanisms for COVID-19 Vaccines

The covid-19 pandemic urgently forced the national funding authorities as well as EU MS to rapidly act on funding and development of COVID-19 vaccines, not only the research and clinical development, but more massively on the production and manufacturing of COVID-19 vaccines to ensure supply of the vaccines. Some of the publicly available information on these mechanisms have therefore been included in this chapter but will be further analysed and described in the final report of the WP7.

### 13) 4.5.1 The European vaccines strategy for COVID-19 Vaccines

The EC responded to the WHO's call for action and helped to raise almost €16 billion since 4 May 2020 under the Coronavirus Global Response, the global action for universal access to tests, treatments, and vaccines against coronavirus and for the global recovery.

The EC presented on 17 June 2020 a European strategy to accelerate the development, manufacturing, and deployment of effective and safe vaccines against COVID-19 (11). In return for the right to buy a specified number of vaccine doses within a given timeframe, the Commission has financed part of the upfront costs faced by vaccines producers in the form of Advance Purchase Agreements (APA). Funding provided is considered as a down-payment on the vaccines that will be purchased by Member States.

Per 7.03.2021, EC had secured up to 2.6 billion doses of COVID-19 vaccines, and as of July 2021, it had secured up to 4.4 billion doses. Negotiations are continuing for additional doses. This payment in advance might not be considered as research funding, but it helped the industry to rapidly develop COVID-19 vaccines, since the member states took the risk of failures. The Commission has also worked with industry to step up vaccine manufacturing capacity. Through APA's with individual vaccine producers, the Commission secured the right to buy a specified number of vaccine doses within a given timeframe and at a given price. In return, the Commission financed a part of the upfront costs from the €2.7 billion Emergency Support Instrument (12). This funding was considered a down-payment on the vaccines that Member States purchase.

Within this strategy the EU has started work to tackle new variants, aiming to rapidly develop and produce effective vaccines against relevant variants of concern on a large scale and has introduced a new instrument, European Health Emergency Preparedness and Response





Authority (HERA) to help respond to this threat. The EU confirmed is participation to the COVAX Facility for equitable access to COVID-19 vaccines on 18 September 2020. to ensure that safe vaccines reach all corners of the world. The Commission and EU countries have pledged close to 3 billion doses to COVAX by August 2021.

The EU Vaccine strategy rests on two pillars:

- Securing sufficient production of vaccines in the EU and thereby sufficient supplies for its Member States through Advance Purchase Agreements (APAs) with vaccine producers via the Emergency Support Instrument (ESI <u>2</u>). Additional financing and other forms of support can be made available on top of such agreements.
- Adapting the EU's regulatory framework to the current emergency and making use of existing regulatory flexibility to accelerate the development, authorisation and availability of vaccines while maintaining the standards for vaccine quality, safety, and efficacy.

Since the high cost and high failure rate make investing in a COVID-19 vaccine a high-risk decision for vaccine developers, the agreements allowed investments that otherwise would simply probably not have happened.

HERA is set up to strengthen Europe's ability to prevent, detect, and rapidly respond to crossborder health emergencies, by ensuring the development, manufacturing, procurement, and equitable distribution of key medical countermeasures. HERA will have at its disposal €6 billion from the EU budget over a 6-year time period. One of the key tasks will be to promote research and innovation to develop effective, safe and affordable medical countermeasures, including diagnostics, therapeutics, and vaccines focused on key and emerging pathogens. HERA will coordinate EU health security before and during crises, bring the EU Member States, industry and relevant stakeholders together and enforce development, production, procurement, stockpiling and equitable distribution of medical countermeasures.

More details on these initiatives and instruments will be further explored throughout the EU-JAV and in the final reports.

## XII- 4.5.2 COVAX Facility - Access to COVID-19 Tools

COVAX was launched in April by the WHO. The COVAX Facility is the vaccine part of the Access to COVID-19 Tools (ACT) Accelerator, a global collaboration to accelerate the development, production, and equitable access to COVID-19 tests, treatments, and vaccines.). Bringing together governments, global health organisations, manufacturers, scientists, private sector, civil society, and philanthropy, with the aim of providing innovative and equitable access to COVID-19 diagnostics, treatments, and vaccines (10). The Commission and EU countries have pledged close to 3 billion doses to COVAX by august 2021.

Coordinated by Gavi, CEPI and WHO, COVAX aims to act as a platform to support the research, development, and manufacturing of a wide range of COVID-19 vaccine candidates and negotiate their pricing. All participating countries, regardless of income levels, will have equal access to these vaccines once they are developed. The initial aim was to have 2 billion doses available by the end of 2021, which should be enough to protect high risk and vulnerable people, as well as





frontline healthcare workers. The EU's participation in COVAX is complementary with the ongoing EU negotiations with vaccine companies launched under the EU Vaccines Strategy. The EU efforts to develop and produce an effective vaccine will benefit all in the global community. The EU investment in scaling up manufacturing capacity will be to the service of all countries in need. Through its Advanced Purchase Agreements, it requires manufacturers to make their production capacity available to supply all countries and calls for the free flow of vaccines and materials with no export restrictions.

The Commission is also coordinating the donation of some of the doses procured by the EU Member States to various partner countries to guarantee their early access to COVD-19 vaccines for health care workers and vulnerable populations until vaccines through COVAX are more widely available.

5 Discussion

# XIII- <u>5.1. EU funding mechanisms and collaboration in vaccine</u> research and development and vaccination research

At the beginning of the EU-JAV, and prior to the covid-19 pandemic, the EU funding mechanisms and collaboration in vaccine research and development and vaccination research were very fragmented. The national research organisations participating in the survey confirmed this and their responses indicate that funding of research and development as well as vaccination research is not evenly distributed along the value chain. The European research funding landscape is complex. In addition to national research organizations, there are several multilateral organizations receiving funding from the member states in an uneven manner. Vaccines with a clear market potential and their development costs are most frequently funded by private sector. Early stage, basic science and late-stage implementation research often utilize public sector funding. Prior to establishment of CEPI, there was a huge lack of funding of research and development of vaccines for the prevention and control of emerging infectious diseases included in the WHO R&D Blueprint list. CEPI was established 2017 as a new instrument for funding vaccine R&D. However, some countries use official development assistance (ODA) financing for this purpose, and these investments are neither aligned with the EU-JAV strategies nor the health strategies for public health purposes from the EU MS ministries of health.

The key focus areas for funding reported by the participating national organisations are general research and development, basic research and pre-clinical development followed by implementation and clinical development in the for vaccines. Some of the organisations finance research on influenza, pandemic influenzas and HPV, but very few or none support research on measles, mumps, rubella or pertussis.

Some of the respondents to the survey wanted to prioritise either EU funding on vaccines for emerging infectious diseases, pandemic vaccines, or vaccines to be used during epidemic outbreaks. Others responded that they wanted to prioritise funding of specific vaccines in the immunisation schedule for which more data on safety and follow-up is needed, and funding of influenza vaccine research due to low vaccine effectiveness. Other comments were that more The content of this document represents the views of the author only and is his/her sole responsibility; it cannot be considered to reflect the views of the European Commission and/or the European Health and Digital Executive Agency (HaDEA) or any other body of the European Union. The European Commission and the Agency do not accept any responsibility for use that may be made of the information it contains.





collaborative funding could be useful for vaccines with little or no commercial interest, where private investments are too low. Examples suggested were on vaccines as a tool to combat AMR, social science and behaviour science, health economy and reimbursement models.

When organisations cooperated, they most frequently mentioned joint calls with other funders as well as bilateral and multilateral cooperation with research funding organisations from other countries. We also tried to understand mechanisms to increase cooperation. To be able to collaborate with other funders, the responders emphasised a need for clear guidance and options for collaborations to be built into their governance system and a joint evaluation and selection process to be in place. Additionally, several of the organisations responded that there was a need for sufficient lead time to approve and agree on topics for calls for proposals as well as alignment of financial rules.

Less than half of the organisations believed a potential future joint European mechanism (i.e., a JPI) would increase collaborative efforts in vaccine R&D and vaccination research; some of the other respondents pointed towards voluntary mechanisms for collaboration as more suitable. One area they mentioned as a particular need for collaboration with the vaccine field was late-stage clinical trials and phase III/phase IV trials.

# XIV- <u>5.2. COVID-19 vaccines as a paradigm for joint funding and</u> <u>new EU instruments?</u>

The main differences between R&D funding prior to the COVID-19 pandemic and today have been the unprecedented speed on vaccine candidate's development, but also the public funding of the manufacturing process by massive public funding and involvement from national and multinational organizations. EU (and its MS) has been the second largest contributor to the R&D investment after the United States. Countries like United Kingdom and Canada have also contributed hugely to the R&D investments. Some of the EU countries have invested more separately than the EU institutions.

The investment is both direct investment to R&D implementers and to public private partnership organisations, where mainly CEPI has been the largest receiver of the public funding to COVID-19 vaccine R&D. The European member states have primarily invested in pharmaceutical companies and ensured manufacturing from their own region/country. This seem to have been political influenced by supporting European workplaces, industrial capital and as a guard against export bans. There are huge differences in the contributed amounts, Germany has been by far the largest European investor and the second largest investor after US. US has taken the same approach to national support, but did not invest in collaborative, multinational organsiations like CEPI or collaborative instruments compared to EU.

European investments in COVID-19 vaccines channeled through CEPI started in early 2020 with contributions from Germany and followed later in 2020 by many other EU MS and non-EU European countries, with the highest investments made in Q2 2020. CEPI's investments (USD 0.9bn) started in January 2020 and reached its maximum level in May 2020 with USD 391 million invested, seemingly faster than EU MS and institutions' direct investments.





As candidates approached late-stage clinical trials and approvals, governments concluded various APAs with producers. The APA timeline seems to follow a similar pattern, as the US started to sign these agreements in Q2 2020, and the EU followed later in Q3 2020. Additionally, the ACT-Accelerator (and its vaccine pillar COVAX) have received substantial support from European countries and institutions and signed its first APA in Q2 2020 (the agreement was signed initially by CEPI but was then included under COVAX's umbrella).

The European commission has addressed the need for new instruments in EU to address fragmentation of countermeasure R&D efforts in the EU, HERA. The development of HERA should be further explored throughout the EU-JAV final reports and is relevant for both WP 6 and WP 7 of the EU-JAV project. Data on direct public investments directed to COVID-19 vaccine development shows a fragmented and slower response from the EU and its MS compared to other actors, such as the US. However, EU and EU MS have contributed to COVAX as well as CEPI.

# XV- 5.3. EU-JAV strategic objectives and outlook

The EU-JAV aims at spurring long-lasting European cooperation against vaccine-preventable diseases and improve population health. The project plans to deliver and share concrete tools for stronger national response to vaccination challenges. There is a need to strengthen interaction of immunisaton information systems to increase vaccine surveillance capabilities, a better understanding of vaccine forecasting, supply and improved preparedness, as well as a better understanding of best practices and interventions to improve confidence in vaccines. However, the findings from WP7 have not identified a clear awareness and interest in financing these strategic objectives.

The lack of funding of research and development of vaccines for the prevention and control of emerging infectious diseases has been improved by organisations like CEPI and the enormous contribution of COVID-19 vaccine funding has resulted in deployment of COVID-19 vaccines to the high and middle-income countries during 2021. Research areas like support of real-world effectiveness of vaccines, implementation of new vaccines in national public health programmes, follow-up of safety signals, long-term safety follow-up and better understanding mechanisms of vaccine hesitancy still lack funding and a coordinated approach among EU MS.

The objective of WP7.1 is to implement a process leading to evidence-based and transparent definition of research priorities in Europe in the field of vaccination research, focusing initially on four "pilot" pre-selected vaccines (pertussis, measles-containing combination vaccines, influenza, and HPV), then expending to all vaccines used in the EU, including against COVID-19. Possibilities for funding mechanisms of these research priorities should be further investigated and explored in the future.

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## Annex

### Annex I: Copy of the survey/Questionnaire

# Questionnaire: Funding of vaccine research and development and vaccination research

The main objective of the EU JAV on vaccine research and development is to define tools and methods for R&D priority setting and identify mechanisms to increase collaboration and cooperation in vaccine research and development and vaccination research. A more specific task is to identify sustainable mechanisms to decrease funding fragmentation and increase the potential for more collaboration and shared funding on common priorities.

An overall review of existing and possible funding mechanisms for vaccine research and development at EU level has been started by the EU-JAV.

This survey targeted towards experts and institutions in charge of setting priorities and funding vaccine research, is developed based on the preliminary input from an overall mapping exercise of financing and funding of vaccine and vaccination research. We therefore ask you as a representative of one of the identified key funding organisations of research and development, to answer this survey and hope that you are able to participate. The survey will take approximately 15-20 minutes.





The combined findings from this survey, the review of existing funding mechanism and input from Stakeholders will be used to propose potential mechanism(s) to increase collaboration in vaccine and vaccination research and cooperation for funding of identified priorities.

This questionnaire begins with some high-level questions (Part A) followed by a few more indepth questions concerning mechanisms for collaboration and shared funding on common priorities (Part B).

To support the development of a prioritisation framework we additionally ask a few questions on your perspective relative to funding vaccine and vaccination research for four pilot vaccines: Measles-containing vaccine, Human Papilloma Virus (HPV), pertussis and influenza vaccines. **Please note:** 

- all questions are optional, if you find the questionnaire too long; please provide comment on those challenges that are most pressing to your organisation.

Deadline: **01.03. 2019**.

Contact Karianne.Johansen@fhi.no if you find any of the questions unclear or need any additional guidance.

Name of the organisation you are completing the review for:

Can we contact you if we have questions about your responses? If so, please fill in your email address and telephone number.

### Part A

### 1. Which research areas does your organisation provide funding for?

- □ All scientific disciplines
- □ Only specific scientific disciplines (please specify)





Others, e.g. infrastructure, educational activities (please specify):

### 2. Which mechanisms do you use to fund research (you can choose multiple options)?

- □ Calls for grant applications
- □ Infrastructure support
- □ Public private partnerships
- □ Collaboration with other funders (please specify)
- □ Joint calls with other funders (please specify)
- Open applications (please specify)
- Others (please specify): \_\_\_\_\_\_
- 3. Which type of research and development does your organisation provide funding for (you can choose multiple options)?
  - Basic research
  - Discovery
  - Pre-clinical development
  - □ Clinical development
  - □ Phase IV and pharmacovigilance studies
  - □ Epidemiological studies
  - □ Social sciences
  - □ Implementation research
  - Others (please specify): \_\_\_\_\_\_

#### 4. Does your organisation fund vaccine research and development (product R&D)?

- □ Yes
- □ No

# 5. If yes, how much of your total funding is dedicated to <u>vaccine research and development (product</u> <u>R&D)</u>?





### □ Please specify a percentage and yearly amount

### 6. Does your organisation fund research on vaccination?

- □ Yes
- □ No
- 7. If yes, how much of your total funding is dedicated to research on vaccination?
  - Please specify a percentage and yearly amount
- 8. Which type of <u>vaccine and vaccination research</u> (including <u>product R&D</u>) does your organisation provide funding for (you can choose multiple options)?
  - □ Basic research
  - Discovery
  - □ Pre-clinical development
  - □ Clinical development
  - □ Phase IV and pharmacovigilance studies
  - Epidemiological studies
  - □ Social sciences
  - □ Implementation
  - Others (please specify): \_\_\_\_\_

# 9. Is your <u>vaccine and vaccination research</u> (including product R&D) funding dedicated to prioritised areas (you can choose multiple options)?

- □ Only specific disease areas (please specify)
- □ Emerging diseases (please specify)





- □ Only diseases with a clear market potential (please specify)
- □ Neglected diseases (please specify)
- □ Antimicrobial resistance (please specify)
- □ Pandemic threats (please specify)
- Others (please specify): \_\_\_\_\_\_
- 10. Has your organisation funded <u>vaccine research or development (product R&D)</u> in one of these areas during the last 2 years (you can choose multiple options)?
  - Influenza virus
  - Pandemic influenza virus
  - □ Human papilloma virus (HPV)
  - □ Measles, mumps or rubella (MMR) virus
  - Pertussis bacteria

Please	specify	the	type	of	funding:

# 11. Has your organisation funded <u>research on vaccination</u> in one of these areas during the last 2 years (you can choose multiple options)?

- Influenza virus
- □ Pandemic influenza virus
- □ HPV virus
- MMR virus
- Pertussis bacteria

Please	specify	the	type	of	funding:





- 12. What type of governance structure is involved in development of calls for proposals/funding opportunities in your organisation (you can choose multiple options)?
  - The Board
  - □ Investment committee
  - □ Scientific advisory committee
  - External experts
  - Internal experts in our organisation
  - Others (please specify the type of governance bodies)
- 13. What type of governance structure is involved in the decision making process for call for proposals/funding opportunities in your organisation (you can choose multiple options)?
  - The Board
  - □ Investment committee
  - Scientific advisory committee
  - External experts
  - □ Internal experts in our organisation
  - Others (please specify the type of governance bodies)

# 14. Which type of eligibility criteria do you use for funding decisions (you can choose multiple options, please specify)?

- Applicants specific geographic location
- Consortiums must be developed
- Public private collaboration requirement
- Co-funding requirements
- In-kind contribution requirements
- Other collaborative requirements
  (please specify)
- Others

(please specify)\_\_\_\_\_





If	you	choose	multiple	options,	please	explain
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#### 15. Do you have experience with collaboration with other funders?

- Yes
- □ No

If yes, please describe type of collaboration

### Part B

# 16. What do you believe are the most important factors needed to be able to collaborate with other funders (maximum 3 options are allowed)?

- Clear guidance and options for collaborations must be built into our governance system
- Joint evaluation and selection process must be in place
- □ Sufficient lead time to approve and agree topics for calls for proposals
- □ Financial rules must be aligned
- A possibility to have split grant agreements or contracts
- □ Agreement of geographic eligibility in advance
- A comprehensive overview of prioritised research areas where collaboration is needed
- An exchange mechanisms for information on prioritised research areas between EU member states and funders
- Other factors (please specify):





- 17. In your opinion, would a potential future joint European mechanism (i.e. a JPI) for funding of vaccine research and development and vaccination research increase collaborative efforts in this area?
  - Yes
  - □ No
  - Unsure

# 18. If yes, should the focus be on specific priority research areas for vaccines and vaccination (including product R&D)? (maximum 3 options are allowed)?

The work package is looking into specific cases for priority setting. Should an EU mechanism for funding on vaccine and vaccination research focus on specific priority vaccines instead of the full range of vaccines in the national immunisation schedule, we ask for your rationale behind the choices:

Emerging infectious diseases (please give examples)
Rarely used vaccines and immunoglobulins (please give examples)
Pandemic vaccines / Vaccines to be used during epidemic outbreaks
Specific vaccines in the immunisation schedule (please give examples)
Vaccines against diseases causing frequent outbreaks today, e.g. measles
Vaccines with low efficacy, e.g. pertussis
Vaccines where more data on safety and follow-up is needed, e.g. HPV
Others (please give examples)

Please include your rationale:





### 19. If yes, what are the best ways to develop collaboration funding mechanism in EU?

- □ Voluntary cooperation between countries
- □ Mandatory implementation through an EU directive
- □ A new Joint Programming Initiative
- Support and aided by draft agreements made by the EC
- □ Others (please specify):