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D 35. Potential mechanisms to increase collaboration in vaccine and vaccination research and cooperation for funding these programmes among MS

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List of abbreviations

AMC	Advance Market Commitment
APA	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.



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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 web-based 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



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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

4.1 Participating organisations to the Survey

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.

Table 1. Organisations that responded to the survey

<i>Organisation</i>	<i>Full name, Geographical Area</i>
<i>EDCTP</i>	European and Developing Countries Clinical Trials Partnership, EU
<i>EWI-Belgium</i>	Governmental Department of Economy, Science and Innovation, Belgium
<i>MRC-UK</i>	Medical Research Council, UK
<i>UoM-Malta</i>	University of Malta, Malta
<i>Vinnova-Sweden</i>	Vinnova – Sweden’s Innovation Agency, Sweden
<i>BELSPO-Belgium</i>	Belgian Science Policy Office, Belgium
<i>ERC-Estonia</i>	Estonian Research Council, Estonia
<i>MoSA-Estonia</i>	Ministry of Social Affairs, Estonia
<i>MoESS-Slovenia</i>	Ministry of Education, Science and Sport, Slovenia



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<i>NCRD-Poland</i>	National Centre for Research and Development, Poland
<i>EC</i>	European Commission, EU
<i>MoHER-France</i>	Ministry of Higher Education and Research, France
<i>NSC-Poland</i>	National Science Centre, Poland
<i>DLR-PT-Germany</i>	DLR-PT, Federal Ministry of Education and Research, Germany

4.2 Overview of other relevant organisations funding vaccine 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

<i>Organisation</i>	<i>Short Description</i>	<i>Type of funding mechanism</i>
<i>Innovative Medicines Initiative (IMI) (4)</i>	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)).
<i>Wellcome (5)</i>	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
<i>Bill & Melinda Gates Foundation (BMGF) (6)</i>	A US-based private foundation, global scope	



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<i>UK Vaccine Network (7)</i>	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	
<i>CEPI (3)</i>	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
<i>Joint Programming Initiative (JPI) Mechanism (8)</i>	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
<i>Global Alliance for Vaccines and Immunization (GAVI) (9)</i>	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.	



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4.3 Results of the survey

4.3.1 Areas and types of research for which responding organisations 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).

<i>Which research areas does your organization provide funding for?</i>	<i>Number of respondents</i>
<i>All scientific disciplines</i>	11
<i>Others, e.g., infrastructure, educational activities</i>	5
<i>Only specific disciplines</i>	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

<i>Organisation</i>	<i>Only specific scientific disciplines (please specify)</i>	<i>Others, e.g., infrastructure, educational activities (please specify):</i>
<i>EDCTP</i>	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
<i>EWI-Belgium</i>	-	European Strategy Forum on Research Infrastructures (ESFRI) agenda, Big equipment, co-financing bio incubators
<i>MRC-UK</i>	Medical research	Infrastructure, educational activities, public engagement, workshops, conferences.
<i>MoSA-Estonia</i>	Health research, social sciences	Specific educational activities in health and social welfare
<i>MoHER-France</i>	-	Infrastructure, higher education, research organisms, universities, regulatory agencies
<i>DLR-PT-Germany</i>	-	e.g., medical/scientific training, biobanks, registries



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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

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



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Figure 1. Presence or absence of funding of vaccine research and development (product R&D) at the responding organisation (N=14)

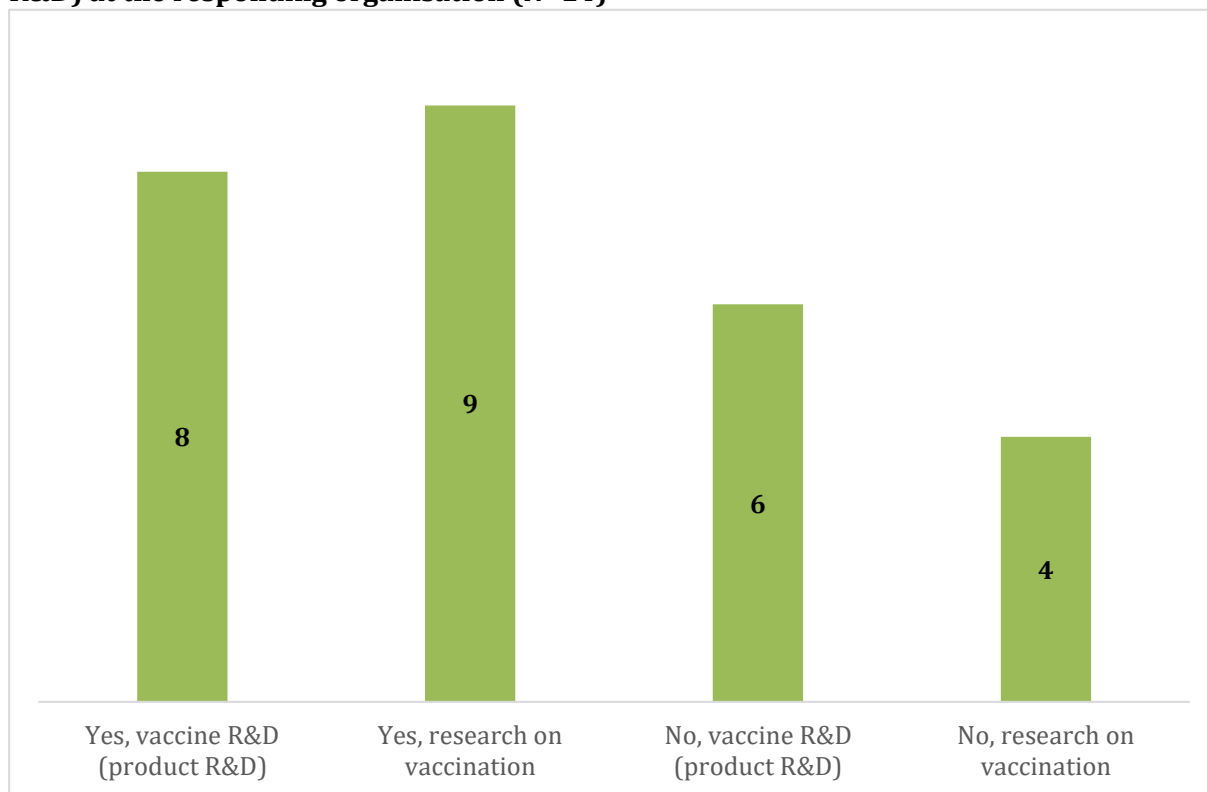


Table 6. Additional feedback on the amount of total funding research and development in these areas

<i>Organisation</i>	
	How much is your total funding of research and development?
<i>EDCTP</i>	Approximately 800 million Euro for the period between 2014-2024 (683 million from the EU + approximately 120 million from partner countries and third parties)
<i>EWI-Belgium</i>	STI budget: 2. 858 billion Euro, of which 1. 6 billion Euro R&D in 2018
<i>MRC-UK</i>	814 million pound per annum



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<i>Vinnova-Sweden</i>	Funding in total 80 million Euro in the health area, not specific funding for vaccines
<i>ERC-Estonia</i>	304 million Euro in 2017
<i>MoSA-Estonia</i>	Funding varies yearly
<i>NCRD-Poland</i>	Around 4 billion Euro
<i>EC</i>	The total budget for the current research and innovation programme H2020 is 77 billion Euro. There is no budget earmarked for vaccine research
<i>MoHER-France</i>	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
<i>NSC-Poland</i>	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)
<i>DLR-PT-Germany</i>	Overall budget of BMBF 18 Billion Euro in 2019
	Please specify a yearly amount for vaccine research and development
<i>EDCTP</i>	Approximately 100 million Euro, 30 % for vaccines
<i>EWI-Belgium</i>	1.6 billion Euro
<i>MRC-UK</i>	approximately 814 million pounds, 2 % for vaccines
<i>UoM-Malta</i>	There is no dedicated amount to vaccine research
<i>ERC-Estonia</i>	125,3 million Euro from the public sector (mainly Estonian Research Council, some part comes directly from Ministries)
<i>MoSA-Estonia</i>	7 million Euro in 2018
<i>MoESS-Slovenia</i>	Annual amount varies. Figures for 2018: 2 million Euro for international collaboration (research projects and European research infrastructure)
<i>NCRD-Poland</i>	around 1 billion Euro
<i>EC</i>	In H2020 (2014-2018) so far for vaccine and vaccination R&D, 490 million Euro have been committed



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<i>MoHER-France</i>	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.
	Please specify a percentage and yearly amount for vaccination research
<i>MRC-UK</i>	Currently 55 million pound per annum (6%)
<i>UoM-Malta</i>	Only if this is a successful project application - none ongoing at present
<i>ERC-Estonia</i>	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
<i>MoSA-Estonia</i>	Funding is project-based and varies yearly; yearly studies on vaccination coverage is performed by Estonian Health Board using internal resources
<i>EC</i>	So far in H2020, 490 million Euro have been committed to vaccine or vaccination R&D
<i>MoHER-France</i>	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.



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

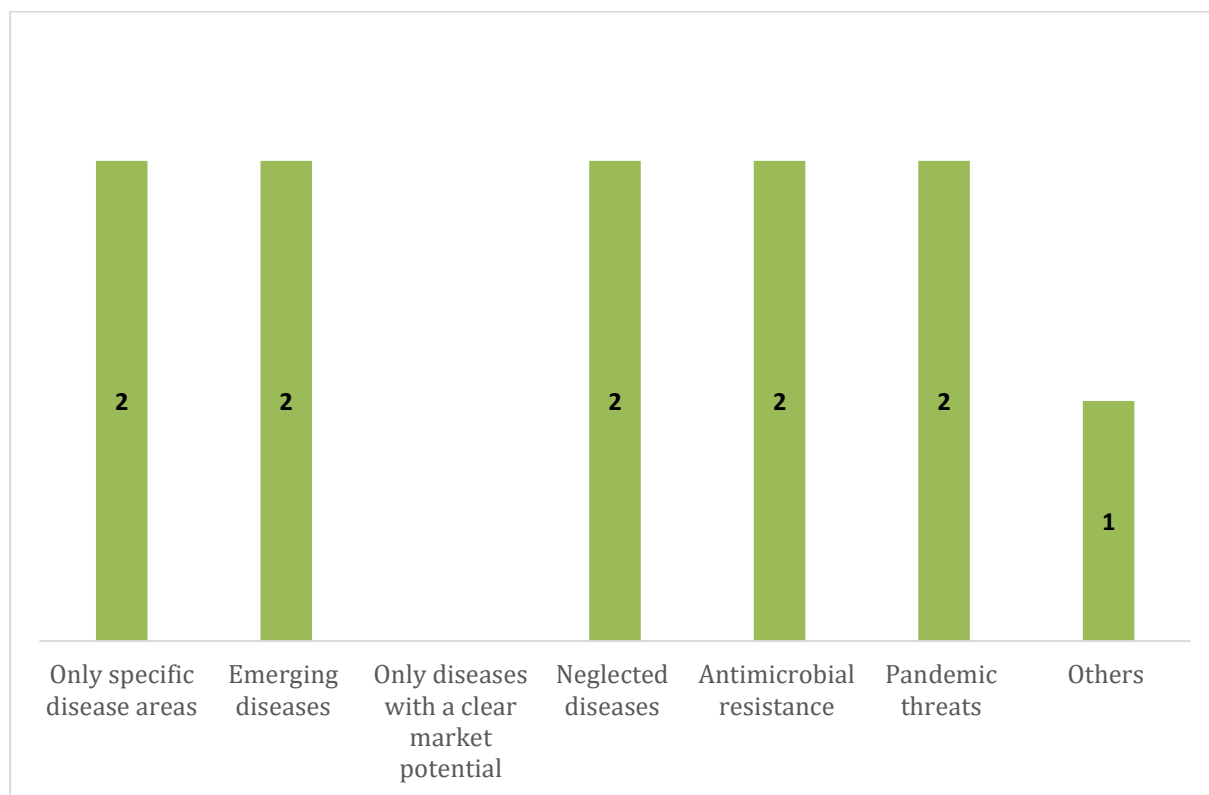


Table 7. Comments to specific priority areas for funding from EDCTP and DLR-PT-Germany

<i>Organisation</i>	<i>Only specific disease areas (please specify):</i>
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.



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	Comments to the topic neglected diseases as a specific prioritised area:
<i>DLR-PT-Germany</i>	They fund Malaria, HIV, TB
	Comments to the topic pandemic threats as a specific prioritised area:
<i>DLR-PT-Germany</i>	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)

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

4.3.2 Funding mechanisms used, collaboration on funding and governance

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



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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.

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

Table 10. Additional comments to funding mechanism

Organisation	Examples of collaboration with other funders
<i>EWI-Belgium</i>	EWI is the overarching ministry that supports the funding agencies FWO and VLAIO
<i>MRC-UK</i>	Wellcome, UK Government departments, Charitable partners
<i>Vinnova-Sweden</i>	Swedish research council
<i>NCRD-Poland</i>	Bilateral cooperation
<i>EC</i>	Collaboration (partnerships (IMI, EDCTP); policy; joint calls). Main partners: Member states, associated countries, third countries, BMGF and other foundations, CEPI, pharma industry
<i>MoHER-France</i>	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.
<i>NSC-Poland</i>	Bilateral and multilateral cooperation with research funding organisations from other countries within different frameworks
<i>DLR-PT-Germany</i>	e.g., CEPI, EDCTP, Grand Challenges Africa



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Joint Calls with other funders	
<i>EDCTP</i>	We collaborate with other organisations to establish a common pot that is used for open calls around a jointly defined research theme
<i>EWI-Belgium</i>	In some cases, we collaborate with FWO and VLAIO
<i>MRC-UK</i>	Wellcome, UK Government departments, Charitable partners
<i>ERC-Estonia</i>	H2020 ERA-Nets
<i>MoESS-Slovenia</i>	Participation in joint transnational calls via ERA-NET Co-funds
<i>NCRD-Poland</i>	ERA-NET programmes, JPI programmes, EJP programmes etc.
<i>EC</i>	We organise ad-hoc joint calls for proposals with other funders, which are published in our H2020 annual work programmes.
<i>MoHER-France</i>	Same as above
<i>NSC-Poland</i>	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)
<i>DLR-PT-Germany</i>	e.g. JPIAMR, ERA-Nets
Open applications	
<i>EWI-Belgium</i>	Sometimes stakeholders bring important issues to our attention and ask for funding
Others	
<i>EWI-Belgium</i>	We also identify important needs and can then provide funding
<i>MoSA-Estonia</i>	Public tenders to carry out R&D activities
<i>MoESS-Slovenia</i>	Collaboration in European research infrastructures; Providing funds for Slovenian Research Agency, which holds national calls for research projects and programmes in all scientific disciplines
<i>NCRD-Poland</i>	venture capital, hub projects
<i>EC</i>	innovation prizes



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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

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

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

<i>Development of calls for proposals</i>	
<i>EWI-Belgium</i>	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
<i>MoESS-Slovenia</i>	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.
<i>EC</i>	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)



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<i>MoHER-France</i>	The MESRI preferentially operates calls through a dedicated funding agency, ANR. Other funding agencies can also operate, and other ministries
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Decision making of calls for proposals	
<i>MoESS-Slovenia</i>	Internal Committee/Working group
<i>NCRD-Poland</i>	Director decision
<i>EC</i>	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.
<i>MoHER-France</i>	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
<i>Applicant specific criteria</i>	7
<i>Consortiums must be formed</i>	7
<i>In kind contribution</i>	4
<i>Public private collaboration</i>	3
<i>Co-funding requirements</i>	3
<i>Other collaborative measures</i>	1
<i>Others</i>	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.



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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.

Table 14. Examples and description of experience with collaborating with other funders.

<i>Organisation</i>	<i>Description of and type of collaboration with other funders</i>
<i>EDCTP</i>	Joint calls: where each funder provides a cash contribution, and a joint call text is developed and joint selection procedure for applications.
<i>MRC-UK</i>	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)
<i>Vinnova-Sweden</i>	Joint call within the health area
<i>ERC-Estonia</i>	EU research partnerships like ERA-Nets, JPIs, some research infrastructure programmes.
<i>MoSA-Estonia</i>	Co-funding of research projects, e.g., with local research council.
<i>MoESS-Slovenia</i>	ERA-NET Co-founds and JPIs.
<i>NCRD-Poland</i>	Bilateral cooperation, ERA-NET scheme, JPI scheme, collaboration with the industry (domestic programmes)
<i>EC</i>	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 ad-hoc calls for R&D
<i>MoHER-France</i>	multinational call between different national agencies or ministries, European Commission tools such as era nets, JPIs, EJPs
<i>NSC-Poland</i>	Bilateral and multilateral cooperation with Research Funding Organisations from different countries within different frameworks, ex. ERA-NET Co-fund programmes
<i>DLR-PT-Germany</i>	CEPI, JPIAMR, EDCTP - Joint funding of vaccine development



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Table 15. Examples and description of need to collaborate with other funders in vaccine research.

<i>Organisation</i>	<i>Examples and description of need to collaborate with other funders in vaccine research</i>
<i>EDCTP</i>	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
<i>MRC-UK</i>	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.
<i>UoM-Malta</i>	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.
<i>ERC-Estonia</i>	European partnerships under umbrella of Framework Programme
<i>MoSA-Estonia</i>	Co-funding schemes with other ministries.
<i>EC</i>	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.
<i>MoHER-France</i>	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.
<i>DLR-PT-Germany</i>	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.

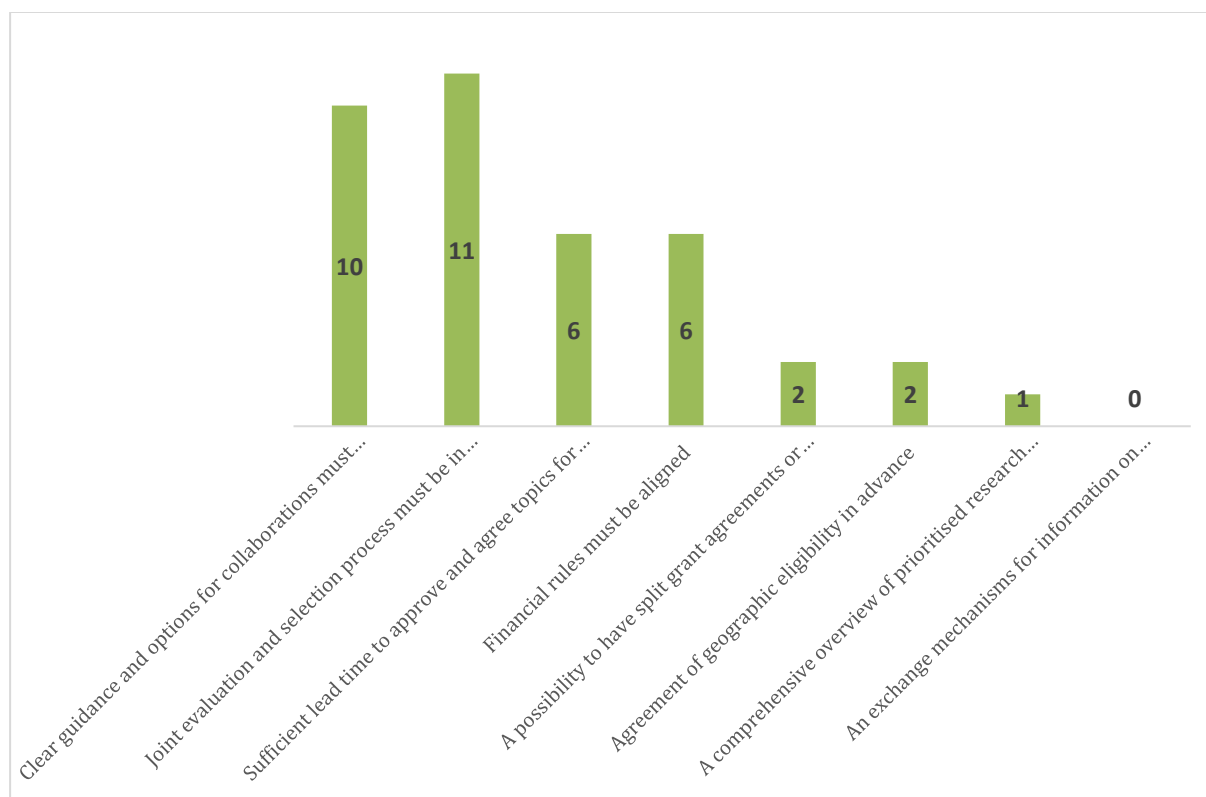


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Figure 3. Most important factors needed for collaboration with other funders (N=14)



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

4.3.3 Would a potential future joint European mechanism increase 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.



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

<i>Organisation</i>	<i>Best ways to develop collaboration funding mechanism in EU</i>
<i>EDCTP</i>	A new Joint Programming Initiative (JPI), Preferably a JPI with a sizeable common pot of funding to allow implementation of activities
<i>MRC-UK</i>	A new Joint Programming Initiative (JPI)
<i>UoM-Malta</i>	A new Joint Programming Initiative (JPI)
<i>Vinnova-Sweden</i>	A new Joint Programming Initiative (JPI)
<i>ERC-Estonia</i>	A new Joint Programming Initiative (JPI)
<i>MoSA-Estonia</i>	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
<i>MoESS-Slovenia</i>	Others, Co-fund mechanisms
<i>EC</i>	Voluntary collaboration between funding agencies
<i>MoHER-France</i>	Support and aided by draft agreements made by the EC
<i>NSC-Poland</i>	Voluntary collaboration between funding agencies

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

<i>Specific priority areas of a future JPI in vaccine R&D and vaccination research.</i>	<i>Number of respondents (N)</i>
<i>Emerging infectious diseases</i>	4
<i>Pandemic vaccines/Vaccines to be used during epidemic outbreaks</i>	4
<i>Vaccines where more data on safety and follow-up is needed e.g., HPV</i>	2
<i>Vaccines with low effectiveness, e.g., influenza</i>	2
<i>Vaccines against diseases causing frequent outbreaks today, e-g- measles</i>	1
<i>Specific vaccines in the immunisation schedule</i>	1
<i>Rarely used vaccines and immunoglobulins</i>	0
<i>Vaccines with low efficacy. E.g., pertussis bacteria</i>	0
<i>Others</i>	3



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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.

4.4 Description of other funding mechanism - selected 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.

4.4.1 Wellcome

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).



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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.

4.4.2 The Bill and Melinda Gates Foundation

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:



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- 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).

4.4.3. Global Alliance for Vaccines and Immunization (Gavi)

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



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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.

4.4.4 UK Vaccine Network

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 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



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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.

4.4.5 Coalition of epidemic preparedness innovation (CEPI)

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



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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).

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 influenza, 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.

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



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funding within the field of vaccine but is included in the overview since this was one of the mechanisms included in the survey.

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.

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 its 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.



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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 2). 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 cross-border 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.

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



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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 COVID-19 vaccines for health care workers and vulnerable populations until vaccines through COVAX are more widely available.

5 Discussion

5.1. EU funding mechanisms and collaboration in vaccine 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



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research due to low vaccine effectiveness. Other comments were that more 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.

5.2. COVID-19 vaccines as a paradigm for joint funding and new EU instruments?

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 organisations 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



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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.

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 immunisation 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 expanding 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



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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 in-depth 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:



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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



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- 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 vaccine research and development (product R&D)?

- 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 vaccine and vaccination research (including product R&D) does your organisation provide funding for (you can choose multiple options)?

- Basic research



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- Discovery
- Pre-clinical development
- Clinical development
- Phase IV and pharmacovigilance studies
- Epidemiological studies
- Social sciences
- Implementation
- Others (please specify): _____

9. Is your vaccine and vaccination research (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 vaccine research or development (product R&D) in one of these areas during the last 2 years (you can choose multiple options)?

- Influenza virus
- Pandemic influenza virus



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- Human papilloma virus (HPV)
- Measles, mumps or rubella (MMR) virus
- Pertussis bacteria

Please specify the type of funding:

11. Has your organisation funded research on vaccination 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



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- 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

15. Do you have experience with collaboration with other funders?

- Yes
- No

If yes, please describe type of collaboration



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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



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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?

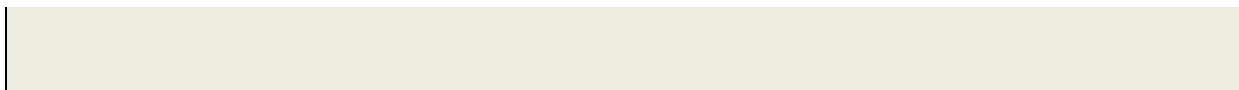
- Voluntary cooperation between countries
- Mandatory implementation through an EU directive
- A new Joint Programming Initiative
- Support and aided by draft agreements made by the EC
- Others (please specify):



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