Brussels, 23 June 2017

COST 042/17

DECISION

Subject: **Memorandum of Understanding for the implementation of the COST Action "European Network of Vaccine Adjuvants" (ENOVA) CA16231**

The COST Member Countries and/or the COST Cooperating State will find attached the Memorandum of Understanding for the COST Action European Network of Vaccine Adjuvants approved by the Committee of Senior Officials through written procedure on 23 June 2017.

MEMORANDUM OF UNDERSTANDING

For the implementation of a COST Action designated as

COST Action CA16231
EUROPEAN NETWORK OF VACCINE ADJUVANTS (ENOVA)

The COST Member Countries and/or the COST Cooperating State, accepting the present Memorandum of Understanding (MoU) wish to undertake joint activities of mutual interest and declare their common intention to participate in the COST Action (the Action), referred to above and described in the Technical Annex of this MoU.

The Action will be carried out in accordance with the set of COST Implementation Rules approved by the Committee of Senior Officials (CSO), or any new document amending or replacing them:

a. "Rules for Participation in and Implementation of COST Activities" (COST 132/14);
b. "COST Action Proposal Submission, Evaluation, Selection and Approval" (COST 133/14);
c. "COST Action Management, Monitoring and Final Assessment" (COST 134/14);
d. "COST International Cooperation and Specific Organisations Participation" (COST 135/14).

The main aim and objective of the Action is to facilitate communication and exchange among adjuvanted vaccine developers and to ensure that new discoveries are disseminated so that their potential can be exploited to the maximum. These objectives aim to increase the ability to best use existing adjuvant technologies and to develop new ones. This will be achieved through the specific objectives detailed in the Technical Annex.

The economic dimension of the activities carried out under the Action has been estimated, on the basis of information available during the planning of the Action, at EUR 44 million in 2016.

The MoU will enter into force once at least five (5) COST Member Countries and/or COST Cooperating State have accepted it, and the corresponding Management Committee Members have been appointed, as described in the CSO Decision COST 134/14.

The COST Action will start from the date of the first Management Committee meeting and shall be implemented for a period of four (4) years, unless an extension is approved by the CSO following the procedure described in the CSO Decision COST 134/14.

TECHNICAL ANNEX

OVERVIEW

Summary
This Action aims to bring together experts and stakeholders from the three main areas of vaccine research: human infectious disease, cancer, and animal disease in order to address one of the most critical steps in vaccine development: the use of adjuvants in vaccine formulations. The ultimate goal is to establish a platform to discuss, share and synergize available knowledge on adjuvants and vaccine formulation, and to coordinate their translation into successful, safe and innovative vaccines. Significant effort will be placed on bridging these three separated vaccine fields. This network will significantly strengthen ongoing EU-funded activities and provide a platform for accelerating the development of affordable and effective vaccines in Europe. In addition, as well as sharing their experiences with each other, the Action participants will also engage the general public, providing impartial, balanced and scientific information on adjuvants and vaccines. This Action will contribute to the strengthening of Europe's position as a global leader in vaccinology, and will increase knowledge across the currently separated fields of vaccine development, as well as providing a repository of information for the European public about vaccines and vaccination.

Areas of Expertise Relevant for the Action	Keywords
● Health Sciences: Infectious diseases ● Clinical medicine: Oncology ● Veterinary science: Veterinary medicine (miscellaneous) ● Clinical medicine: Prevention and treatment of infection by pathogens (e.g. vaccination, antibiotics, fungicide)	● Adjuvant ● Vaccine ● Formulation ● Delivery system

Specific Objectives
To achieve the main objective described in this MoU, the following specific objectives shall be accomplished:

Research Coordination
● Collect information about existing adjuvants (availability, manufacturer, IP rights, available quality/grade, mode of action, type of immune response modulated, publications, clinical trials, formulation techniques, characterisation assays).
● Harmonize protocols for preclinical testing and down selection.
● Collect guidelines/regulations on the use of adjuvants for different groups of vaccines (prophylactic, therapeutic, veterinary vaccines).
● Coordinate discussions on specific scientific topics in the European adjuvant field, resulting in the preparation of a set of recommendations for improvements to the regulatory landscape.
● Develop strategies to improve existing adjuvant-based formulations (as well as excipients, preservatives etc.).
● Promote progress in existing research projects on vaccine adjuvants.
● Establish an online database describing adjuvants, which will be publicly accessible. This will allow researchers and the general public to access a wide-ranging body of knowledge on the topic.
● Develop scale-up procedures for adjuvant production
● Develop assays for the characterization of antigen-adjuvant formulations.

Capacity Building
● Set up a platform, which gathers know-how on adjuvants and vaccine formulation, and makes it available to the European vaccine R&D community at large.
● Facilitate access to adjuvants and protocols for preclinical testing.
● Help Early Career Investigators to access and develop new networks, maintain and strengthen existing

links, meet experts and stakeholders, create new opportunities for potential collaborations, and communicate with the European public.
● Bridge different vaccine fields (prophylactic, therapeutic, and veterinary vaccines).
● Strengthen and expand links among vaccine researchers and vaccine developers.

1) S&T EXCELLENCE

A) CHALLENGE

I) DESCRIPTION OF THE CHALLENGE (MAIN AIM)

Vaccines are one of the most cost-effective tools for the control of infectious human and animal disease. Effective and safe vaccines continue to make an invaluable contribution to public and animal health worldwide, and the ongoing development of these vaccines has seen some remarkable achievements over the last decades. Despite a great deal of success in the control of several infectious diseases, there are still many for which there are no effective vaccine. Of particular significance to Europe are HIV/AIDS, Tuberculosis, herpes virus infections, hepatitis, cancer, bovine respiratory syncytial virus and eimeria, as well as the ever-present rise of new threats such as zika and pandemic influenza. Modern vaccine antigens tend to possess excellent safety profiles due to their purity and well-defined nature. However, this high degree of purity and specificity usually results in poor immunogenicity. In order to remedy this, investigating the inclusion of adjuvants in vaccine formulations has become commonplace with vaccine developers. Adjuvants are substances that, when mixed with vaccine antigens, enhance the immune responses to the antigen, and they are subsequently becoming an essential feature of modern vaccine development. Adjuvants also allow antigen dose sparing, which can dramatically reduce vaccine-manufacturing costs and increase the number of available vaccine doses for a given manufacturing capacity. Furthermore, certain adjuvants can modulate the immune response in vaccinated individuals making adjuvanted vaccines particularly relevant to the elderly, young children and patients with chronic disease. Whilst a modest amount of research has focused on developing new (and improving old) adjuvants, their use in human and animal vaccines remains challenging. The use of suitable adjuvants and adjuvant technology remains mostly in the hands of a few large vaccine manufacturers. These challenges have recently been recognized by both the WHO and several major funding agencies as a priority area to be addressed in vaccine development.

II) RELEVANCE AND TIMELINESS

The world's major vaccine manufacturers produce 90% of their vaccines in Europe and export 84% of their production. Approximately 127 vaccines are currently in development, including 29 in Phase III. Recognising the relevance of effective and safe vaccines as an essential public health tool, several funding agencies have provided significant amounts of funding to support vaccine-related projects. Realising the importance of vaccines for public health and economic growth, the EU has previously supported the design of harmonised procedures to permit pre-clinical selection of vaccine adjuvants (PHARVAT). In addition, the EU has supported specific research infrastructures on vaccines, which have included adjuvant-related activities. This support has included access to antigen/adjuvant formulation services and training courses on adjuvant formulation (e.g. TRANSVAC, ADITEC, EURIPRED, SAPHIR, TBVAC2020, EAVI and EHVA projects). However, these programs do

not provide a framework to network, maintain, and expand a collaboration of adjuvant users within Europe. Such a structure, with a focus on adjuvants and adjuvant technologies, would facilitate sharing of know-how beyond the well-defined scope of specific projects, and would promote dissemination of knowledge, protocols and adjuvants. Addressing this problem is particularly timely within Europe, as the EU is currently funding a number of vaccine-related projects as part of H2020, and in 2017 several other vaccine-related projects have started. Initiating a network to bring together experts and stakeholders from different areas of vaccine research (infectious diseases, cancer, veterinary diseases etc.) with the ultimate goal of establishing a platform to pool and share available knowledge on adjuvants and vaccine formulation, and to coordinate its translation into successful vaccines is particularly timely. Such a network would significantly strengthen ongoing EU-funded activities and provide a platform for the creation of safe, affordable, and effective vaccines for Europe. At present, no similar network currently exists. A loosely similar activity was previously set up by the WHO in the form of GADI (global adjuvant development initiative) who established “Adjunet”, which aimed to minimize the duplication of adjuvant studies, and to ensure that adjuvanted vaccines were made available to resource-constrained countries. However, this activity, which initially proved highly popular, no longer runs due to lack of funding. Furthermore, in light of the rise of the anti-vaccination lobby, which often falsely criticises the use of adjuvants, there is a need to set up a public communication website clearly explaining the science behind the use of adjuvants.

B) SPECIFIC OBJECTIVES

This COST Action has two main objectives. The first is to improve communication among adjuvant developers and between adjuvant developers and the general public. Existing adjuvant expertise/techniques/reagents will be shared amongst the members of the Action and a public communication website explaining adjuvants and their purposes will be set up. The second objective will be to ensure that new discoveries are disseminated so that their potential can be exploited to the maximum. These objectives aim to increase the ability of network members to best use existing technologies and to develop new ones.

I) RESEARCH COORDINATION OBJECTIVES

This grouping of tasks will aim to synergise existing expertise, discuss recent developments, and identify the current state of the art in the field of adjuvants and vaccine formulation by bringing together experts, researchers, and stakeholders to:

- Collect information about existing adjuvants (availability, manufacturer, IP restrictions, available quality/grade, modes of action, types of immune response modulated, publications, clinical trials, formulation techniques, characterisation assays).
- Develop scale-up procedures for adjuvant production.
- Harmonize protocols for preclinical testing and down selection.
- Develop assays for the characterisation of antigen-adjuvant formulations.
- Collect guidelines/regulations on the use of adjuvants for different groups of vaccines (prophylactic, therapeutic, veterinary vaccines).
- Coordinate discussions with experts on specific scientific topics in the European adjuvant field, resulting in the preparation of a set of recommendations for improvements to the regulatory landscape.
- Develop strategies to improve existing adjuvant-based formulations (as well as excipients, preservatives etc.).
- Establish an online database describing adjuvants, which will be publicly accessible. This will allow researchers and the general public to access a wide-ranging body of knowledge on the topic. Action members will be able to modify and add to the information as the body of knowledge evolves and grows.
- Promote progress in existing research projects on vaccine adjuvants.

II) CAPACITY-BUILDING OBJECTIVES

This grouping of tasks aims to establish and strengthen communication networks between adjuvant developers and between adjuvant developers and the general public.

- Set up a platform, which gathers know-how on adjuvants and vaccine formulation, and makes it available to the European vaccine R&D community at large.
- Facilitate access to adjuvants and protocols for preclinical testing.
- Bridge different vaccine fields (prophylactic, therapeutic, and veterinary vaccines).
- Strengthen and expand links among researchers and vaccine developers.
- Help Early Career Investigators to access and develop new networks, maintain and strengthen existing links, meet experts and stakeholders, create new opportunities for potential collaborations, and communicate with the European public.

C) PROGRESS BEYOND THE STATE-OF-THE-ART AND INNOVATION POTENTIAL

I) DESCRIPTION OF THE STATE-OF-THE-ART

Adjuvants for prophylactic vaccines: At present a small number of adjuvants are approved for use in human prophylactic vaccines. Translating adjuvant innovation into novel human vaccines has previously been a lengthy and complicated process. However, with recent clarification of the guidelines for adjuvanted vaccine licensure, the use of adjuvants will rapidly expand. For a growing number of diseases e.g. tuberculosis and malaria, novel adjuvants appear to be essential to confer adequate protection from infection and/or disease. Improving existing vaccines using novel adjuvants and developing a capacity for responding to new epidemics/pandemics is of key importance.
Adjuvants for use in cancer research: Despite several attempts to develop vaccines for cancer therapy, therapeutic vaccines have not yet seen widespread use. Poor immunogenicity of tumor antigens and the immune-compromised status of patients strongly argue in favour of using novel adjuvants, which can modulate the required range of immune responses needed to control and eradicate tumors. One challenge with adjuvants for cancer therapy is that ideally strong inducers of IFN-I and Th1-type responses would be employed to support CTL function. The systemic application of adjuvants / TLR agonists that support this type of response is however problematic and TLR agonists such as imiquimod are currently only able to be used topically.
Adjuvants for veterinary vaccines: Veterinary vaccines share a common goal with human vaccines. Importantly, veterinary vaccines increase cost effectiveness of livestock production methods, improve animal welfare, and play a key role in preventing human infections by animal-derived pathogens (including zoonoses and pandemics). Veterinary vaccines often have suboptimal efficacy or induce only short-term protection, calling for repeated immunisations. Furthermore, the cost effectivity of veterinary vaccination is a key factor, and drives the need for low-cost vaccines where adjuvants can likely play a significant role.

II) PROGRESS BEYOND THE STATE-OF-THE-ART

Adjuvants for prophylactic vaccines: Novel strategies supported by this COST Action will focus on the improvement of existing adjuvant-based formulations to enhance efficacy, safety and stability. There will also be a focus on innovation, especially when considering the diseases for which current adjuvants are not thought to be useful for improving immune responses. The application of adjuvants to vaccines for diseases for which there are currently only experimental vaccines will strengthen the chances of eventually developing a licenced vaccine. A protocol will be developed, based on the existing body of knowledge, that will guide researchers through the different types of adjuvants and allow them to make a rational selection of the most appropriate adjuvants, based on the required immune profile of

their vaccines. This will allow adjuvanted vaccines to be tailored to give the most appropriate immune responses.
Adjuvants for use in cancer research: Due to the life threatening nature of cancer, this is one area where a range of new adjuvant approaches urgently needs to be investigated. A full list of suitable cancer-relevant adjuvants, their properties, grades, IP constraints, and immunomodulation profile will be prepared along with protocols for use, hopefully significantly accelerating progress in this field. This will allow cancer vaccine research to benefit from the extensive body of knowledge existing in human and veterinary vaccination. In addition, novel ways to administer adjuvants in order to limit their action to the tumour tissue will be discussed.
Adjuvants for veterinary vaccines: The increased usage of adjuvants will lead to further cost-reductions in manufacturing adjuvanted veterinary vaccines. The increased inclusion of adjuvants will also lead to the preparation of more effective and safe vaccines.
General progress beyond the state of the art: sharing of knowledge and results, agreeing on best practices, and building a sustainable network will benefit all institutions working in the adjuvanted vaccine field.

III) INNOVATION IN TACKLING THE CHALLENGE

Innovation will be fostered through the increased access of vaccine researchers to adjuvant technology. This will directly contribute to the development of improved and new adjuvanted vaccines as well as promoting the discovery of new adjuvants. Increased public communication will result in increased demand for vaccines, leading to increased profitability and increased funding for R&D.

D) ADDED VALUE OF NETWORKING

I) IN RELATION TO THE CHALLENGE

Extensive adjuvant and adjuvanted vaccine expertise currently exists within Europe. However, this experience is fragmented and spread over numerous organisations with no focal point for synergy. Likewise, several EU-funded vaccine/adjuvant development projects exists but none will bring together Europe's adjuvant expertise into one single critical mass. Therefore, bringing together these groups in a coordinated, harmonious and enabling way provides the most cost and time effective tool for disseminating and supporting existing European expertise and enabling innovation.

II) IN RELATION TO EXISTING EFFORTS AT EUROPEAN AND/OR INTERNATIONAL LEVEL

The EU has supported several research infrastructures and projects involving vaccines and adjuvants. These activities have included access to formulation services and training courses on adjuvant formulation (TRANSVAC, ADITEC, EURIPRED, SAPHIR, TBVAC2020, EHVA, EAVI2020) as well as for the design of harmonised procedures to permit preclinical selection of vaccine adjuvants (PHARVAT). The fact that the EU needs to fund groups specifically for access to adjuvant formulation technology indicates the significant need for this type of technology in Europe. This COST Action aims to strengthen the adjuvant technology accessible by all research groups, not just those able to access this technology through EU-funded projects. Furthermore, these programs do not provide a networking framework that supports the uniting of all people working in the field of adjuvanted vaccines. This Action would facilitate the establishment and running of such a network, allowing the sharing of know-how beyond the restricted scope of specific projects.

2) IMPACT

A) EXPECTED IMPACT

I) SHORT-TERM AND LONG-TERM SCIENTIFIC, TECHNOLOGICAL, AND/OR SOCIOECONOMIC IMPACTS

This Action aims to support the vaccine development community with advice, information, protocols, and training on how to use adjuvants and how to formulate vaccines, complementing and strengthening previous and existing EU-funded projects. The network will support both the development of human and veterinary vaccines aiming to control infectious disease including those with epidemic/pandemic potential. Thus the network is expected to have an impact on both human and animal health through the design of better vaccines and the design of more cost effective vaccines for veterinary use.
One of the main scientific benefits of this COST Action is the sharing of existing know-how about different adjuvants. This will help researches to design and define adjuvants in order to improve vaccine effectiveness especially in low- and non-responding populations, and for individuals with a high-risk of developing complications, such as the elderly and very young.
In summary, this COST Action will contribute to strengthen Europe's position as a leader in vaccinology, and will increase knowledge of the European public about vaccines and vaccination.

B) MEASURES TO MAXIMISE IMPACT

I) PLAN FOR INVOLVING THE MOST RELEVANT STAKEHOLDERS

The most relevant stakeholders for this Action are experts working on adjuvants and in vaccine development. The Action will involve participants in the adjuvant and vaccine formulation field and the major vaccine stakeholders and networks in Europe. A number of additional relevant stakeholders will be contacted to ensure an appropriately broad range of stakeholder involvement. Furthermore, upon starting the Action, a position paper will be published within the first year in a major journal aiming to reach out to stakeholders outside of the members' networks.
The first symposium will be organized towards the end of the first year and will aim to inform stakeholders on the Action activities (the meeting will be advertised and open to all). The participants of the planned symposia and training schools will be informed about the Action's activities and will be invited to participate.
Finally, dissemination material such as posters and presentations will be prepared and presented to stakeholders at conferences and other scientific events, raising awareness of the Action in different target groups and attracting additional stakeholders to participate in the Action.

II) DISSEMINATION AND/OR EXPLOITATION PLAN

Upon the start of the Action a Communication and Dissemination Group will be established with the task to organise the Action's communication, dissemination and exploitation activities. A communication concept will be developed at the beginning of the Action, in order to support the Action outreach to stakeholders.
Action website: One of the first tasks will be the setting-up of the Action website. The Communication and Dissemination Group will collect input from all Action members, and compile related documents on the Action website. The Action website will be constantly updated and will work as the main interface between the Action, scientific community, and general public.
Dissemination material: A corporate design (Action logo) will be developed to define the overall visual identity of the Action. Templates for presentations, reports, and posters will be developed for conferences and meetings. Dissemination material, such as an Action poster

and short presentation will be designed and provided to Action members for Action-related communication and dissemination.
Scientific publications: All scientific outcomes and Action results will be widely disseminated (e.g. through the Action website). Scientific publications relating to Action results will be published in open-access peer-reviewed journals.
Action Symposia: Three symposia are planned to be org anized by the Action. Each symposium will focus on specific topics in order to support the Action's scientific activities, such as "adjuvants for prophylactic vaccines", "adjuvants for therapeutic vaccines" and "adjuvants for veterinary vaccines". Symposia will be used to disseminate and discuss the Action results with relevant stakeholders.
Short-Term Scientific Missions and training: Short-Term Scientific Missions and training schools will strengthen the collaboration between researchers and will help to disseminate know-how on relevant methods, techniques and instruments.
Conferences: Action results will be presented at international scientific conferences such as the Modern Vaccines, Adjuvants & Delivery Systems (MVADS meetings), Annual World Vaccine Congress, and the VaxInEU conference aiming to provide a direct interaction with other members of the scientific community.

C) POTENTIAL FOR INNOVATION VERSUS RISK LEVEL

I) POTENTIAL FOR SCIENTIFIC, TECHNOLOGICAL AND/OR SOCIOECONOMIC INNOVATION BREAKTHROUGHS

This Action will contribute to accelerating adjuvant and adjuvanted vaccine development by exchange of know-how. The Action itself carries very few risks, as it will include participants that will contribute to the activities toward the achievement of the Action objectives. Socioeconomic factors will include increased feasibility of animal vaccination due to lower cost of vaccines resulting in healthier animals, a reduction in the likelihood of zoonosis, and a reduction in the use of antibiotics. Innovative adjuvanted cancer vaccines will reduce the burden of disease.

3) IMPLEMENTATION

A) DESCRIPTION OF THE WORK PLAN

I) DESCRIPTION OF WORKING GROUPS

The scientific program will be structured in Working Groups (WGs). Strong collaborations between the WGs will be encouraged in order to achieve the Action's objectives.

WG 1: "Adjuvants for use in human prophylactic vaccines" will: a) gather information relating to adjuvants currently approved for use in human prophylactic vaccines and provide access to formulation know-how of such adjuvants including possible improvements; b) identify and facilitate access to adjuvants which are in advanced stages of development as well as to novel adjuvants; c) facilitate access to adjuvant technologies and know-how through training schools, Short-Term Scientific Missions, and symposium.
Tasks:
T1.1 Review on which gaps to be addressed.
T1.2 Develop detailed work program.
T1.3 Collect information on adjuvants approved for use in human prophylactic vaccines.
T1.4 Collect information on adjuvants under development for human prophylactic vaccines.
T1.5 Collect guidelines/regulations on the use of adjuvants for human prophylactic vaccines.
T1.6 Organize Short-Term Scientific Missions.
T1.7 Organize training schools.
T1.8 Organize symposium.

Deliverables:
D1.1 Report on gaps in development of adjuvants for use in human prophylactic vaccines.
D1.2 Work program for WG1 (adjuvants for use in human prophylactic vaccines) established.
D1.3 Report on the main outcomes of the symposium organized during year 2.
Milestones:
M1.1 Information on adjuvants approved for use in human prophylactic vaccines collected.
M1.2 Information on adjuvants under development for human prophylactic vaccines collected.
M1.3 Guidelines/regulations on the use of adjuvants for human prophylactic vaccines collected.

WG 2: "Adjuvants for use in human cancer vaccines" will: a) gather information relating to adjuvants currently approved for use in human therapeutic vaccines and provide access to formulation know-how of such adjuvants including possible improvements; b) identify and facilitate access to adjuvants which are in advanced stages of development as well as to novel adjuvants; c) facilitate access to adjuvant technologies and know-how through training schools, Short-Term Scientific Missions, and symposium.
Tasks:
T2.1 Review on which gaps to be addressed.
T2.2 Develop detailed work program.
T2.3 Collect information on adjuvants approved for use in human therapeutic vaccines.
T2.4 Collect information on adjuvants under development for human therapeutic vaccines.
T2.5 Collect guidelines/regulations on the use of adjuvants for human therapeutic vaccines.
T2.6 Organize Short-Term Scientific Missions.
T2.7 Organize training schools.
T2.8 Organize symposium.
Deliverables:
D2.1 Report on gaps in development of adjuvants for use in human cancer vaccines.
D2.2 Work program for WG2 (adjuvants for use in human cancer vaccines) established.
D2.3 Report on the main outcomes of the symposium organized during year 2.
Milestones:
M2.1 Information on adjuvants approved for use in human therapeutic vaccines collected.
M2.2 Information on adjuvants under development for human therapeutic vaccines collected.
M2.3 Guidelines/regulations on the use of adjuvants for human therapeutic vaccines collected.

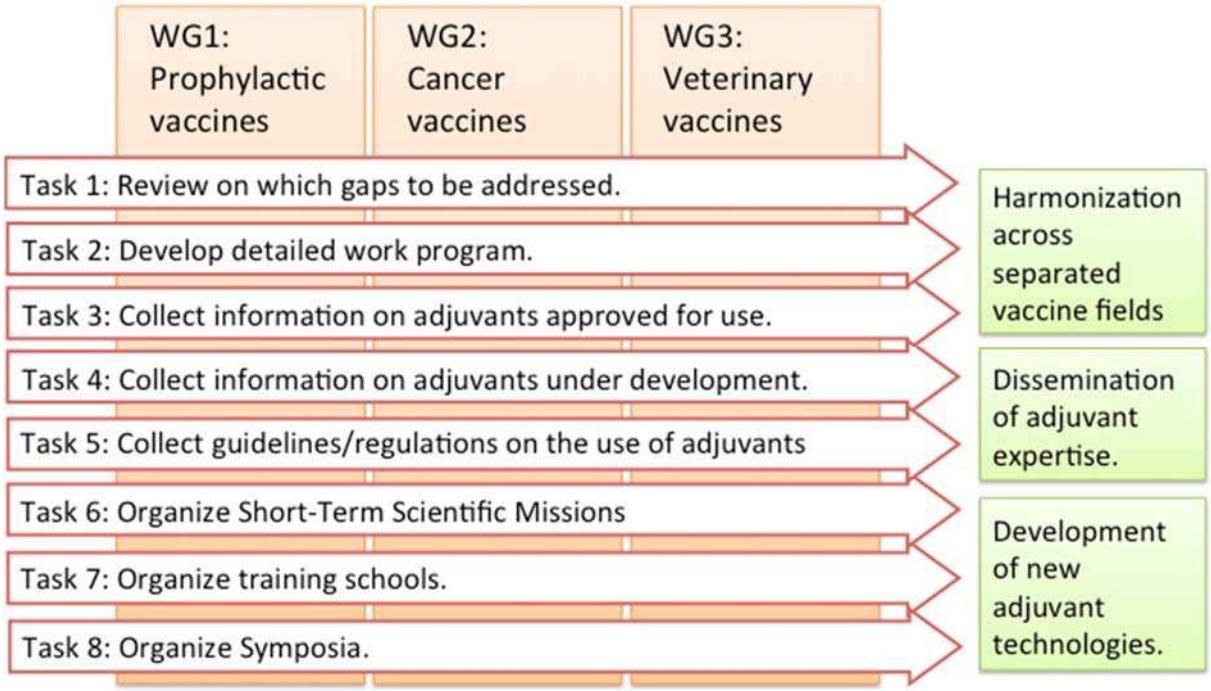
WG 3: "Adjuvants for use in veterinary vaccines" will: a) gather information relating to adjuvants currently approved for use in veterinary vaccines and provide access to formulation know how of such adjuvants including possible improvements; b) identify and facilitate access to adjuvants which are in advanced stages of development as well as to novel adjuvants; c) facilitate access to adjuvant technologies and know-how through training schools, Short-Term Scientific Missions, and symposium.
Tasks:
T3.1 Review on which gaps to be addressed.
T3.2 Develop detailed work program.
T3.3 Collect information on adjuvants approved for use in veterinary vaccines.
T3.4 Collect information on adjuvants under development for veterinary vaccines.
T3.5 Collect guidelines/regulations on the use of adjuvants for veterinary vaccines.
T3.6 Organize Short-Term Scientific Missions.
T3.7 Organize training schools.
T3.8 Organize symposium.
Deliverables:
D3.1 Report on gaps in development of adjuvants for use in veterinary vaccines.
D3.2 Work program for WG3 (adjuvants for use in veterinary vaccines) established.
D3.3 Report on the main outcomes of the symposium organized during year 3.

Milestones:
M1.1 Information on adjuvants approved for use in veterinary vaccines collected.
M1.2 Information on adjuvants under development for veterinary vaccines collected
M1.3 Guidelines/regulations on the use of adjuvants for veterinary vaccines collected.

II) GANTT DIAGRAM

Activities	Year 1				Year 2				Year 3				Year 4			
	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
Annual Network meetings																
Management Committee Meeting																
Working Group Meetings																
Communication and Dissemination Group Meeting																
Task .1: Review on which gaps to be addressed and how																
D1.1: Report on gaps (prophylactic vaccines)																
D2.1: Report on gaps (cancer vaccines)																
D3.1: Report on gaps (veterinary vaccines)																
Task .2: Develop detailed work program																
D1.2: Work program WG1 established																
D2.2: Work program WG2 established																
D3.2: Work program WG3 established																
Task .3: Collect information on adjuvants approved for use																
Milestone 1: Information on adjuvants approved for use collected																
Task .4: Collect information on adjuvants under development																
Milestone 2: Information on adjuvants under development collected																
Task .5: Collect guidelines/ regulations on the use of adjuvants																
Milestone 3: Guidelines/ regulations on the use of adjuvants collected																
Task .6: Organize Short-Term Scientific Missions																
Task .7: Organize training schools																
Task .8: Organize Symposia																
D1.3: Report on Symposium outcome (prophylactic vaccines)																
D2.3: Report on Symposium outcome (cancer vaccines)																
D3.3: Report on Symposium outcome (veterinary vaccines)																

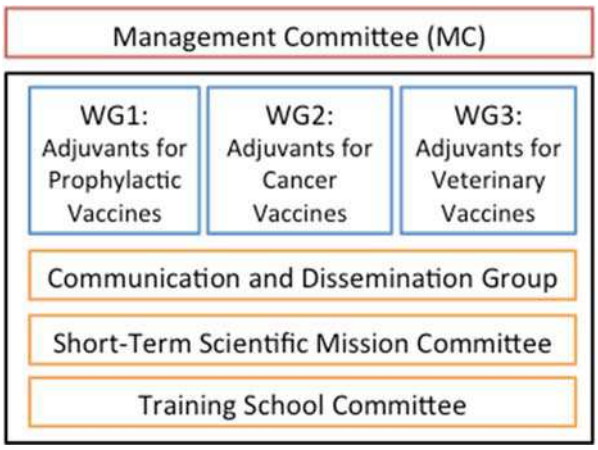
III) PERT CHART (OPTIONAL)



IV) RISK AND CONTINGENCY PLANS

Risk planning, identification and mitigation will be an ongoing process throughout the Action. As an agenda item at all meetings, risks will be identified, have a named owner, and potential mitigation strategies discussed, ranked, and monitored in an ongoing fashion. Failure to agree on recommendations or courses of action leading to divisions pose one of the greatest threats. Although such a threat is considered unlikely, written procedure for solving conflicts will be prepared at the start of the Action and agreed by all participants.

B) MANAGEMENT STRUCTURES AND PROCEDURES



The Management Committee (MC), composed of up to two members of each participating country, will coordinate the overall management of the Action. During the first MC meeting the Management Committee will elect the Action Chair and the Vice Chair; the Chair will be responsible for coordinating the Action activities in line with the scientific objecitives defined in the MoU and the Work and Budget Plan. In addition, the Management Committee will elect Working Group Leaders and then decide on the composition of the three Working Groups. Furthermore, the Management Committee will set up a Communication and Dissemination Group, and a Short-Term Scientific Mission Coordinator / Committee and Training School Committee. The MC will also select the the Grant Holder.

Management Committee: The Management Committee will prepare a detailed Work and Budget Plan for each Grant Period and will make sure that the Action progress will be documented in progress reports. The MC will communicate through regular conference calls and email, but will come together at least once per year.

Working groups: Working Group Leaders will coordinate the scientific activities and provide input for the preparation of scientific reports and present the progresses of the WGs to the MC. Working groups will hold monthly teleconferences and will meet face-to-face twice a year.
Short-Term Scientific Missions (STSM) Coordinator / Committee: The MC will appoint amongst its members a STSM Coordinator and a STSM Committee that will ensure that the application and selection processes are in line with the COST rules. STSMs. The STSM Committee will be responsible for defining, with the agreement of the MC, transparent criteria of evaluation of STSM applications (gender balance, enabling early career investigators, and broadening geographical inclusiveness) and the evaluation of STSM applications. The STSM Committee will hold teleconferences on an ad-hoc basis. In addition, they will prepare notes to outline the activities every three months and communicate the selection of STSM grantees to the Action MC in subsequent MC meetings.
Training Schools Committee: The MC will appoint amongst its members a Training School Committee. This Committee will be responsible for defining, with the agreement of the MC, transparent criteria for the selection of training applications (gender balance, enabling early career investigators, broadening geographical inclusiveness) and will hold teleconferences on an ad-hoc basis.
Communication and Dissemination group: This group will coordinate all communication and dissemination activities of the Action. The group will hold monthly teleconferences and will work closely together with the Working Groups in order to support the transfer of knowledge between Action participants and between the Action participants and the scientific community.

C) NETWORK AS A WHOLE

Completion of the aims of this ambitious Action requires bringing together complementary expertise from a variety of sectors including vaccine R&D, management, communication, and innovation. During the planning of this Action the network mobilised a comprehensive collection of leading institutions, comprising public research institutions, SMEs, regulators and international agencies. This network will be able to provide all of the expertise and resources required to achieve the objectives of the Action. Expertise that was covered during the planning of the Action includes, for example, immunology, epidemiology, systems biology, project management, adjuvant formulation, delivery platforms, GMP manufacture, and clinical trials. During the planning of the Action the network included members with proven and successful track records in basic research, translational vaccine research, development and innovation, but also a number of early- to mid-career researchers who will be encouraged to take leading roles in the network. This Action will implement the COST Excellence and Inclusiveness Policy.