Good Practice Guidance
Module 2: Governance models

WP1 – Best practice and code of conduct for benefit-risk monitoring of vaccines

Deliverable 1.5
Initial conceptual model for public-private interaction

V 1.6 Final draft
11 May 2015
This is a deliverable of the ADVANCE Project (Grant Agreement number 115557; http://www.advance-vaccines.eu), which is a European Public-Private Partnership funded under the Innovative Medicines Initiative (IMI).

ADVANCE vision is focused to deliver “best evidence at the right time to support decision-making on vaccination in Europe”. Our mission is to prototype a sustainable and compelling system that rapidly provides best available scientific evidence on vaccination benefits and risks post-licensure for well informed decisions. This will be achieved by developing and testing a code of conduct, rules of governance, technical infrastructures, data sources, methods, and workflows in a European network of stakeholders.

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Key words
Governance, multi-stakeholders initiatives/interactions, collaboration, partnerships.

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Participants of the ADVANCE Consortium are referred to herein according to the following codes:

- AUH. Aarhus Universitetshospital (Denmark)
- AEMPS. Agencia Española de Medicamentos y Productos Sanitarios (Spain)
- ASLCR. Azienda Sanitaria Locale della Provincia di Cremona (Italy)
- CRX. Crucell Holland BV (Netherlands)
- ECDC. European Centre for Disease Prevention and Control (Sweden)
- EMA. European Medicines Agency (United Kingdom)
- EMC. Erasmus Universitair Medisch Centrum Rotterdam (Netherlands) - Coordinator
- GSK. GlaxoSmithKline Biologicals, S.A. (Belgium) - EFPIA Coordinator
- KI. Karolinska Institutet (Sweden)
- LSHTM. London School of Hygiene and Tropical Medicine (United Kingdom)
- OU. The Open University (United Kingdom)
- MHRA. Medicines and Healthcare products Regulatory Agency (United Kingdom)
- NOVARTIS. Novartis Pharma AG (Switzerland)
- PEDIANET. Società Servizi Telematici SRL (Italy)
- PFIZER. Pfizer Limited (United Kingdom)
- P95. P95 (Belgium)
- RCGP. Royal College of General Practitioners (United Kingdom)
- RIVM. Rijksinstituut voor Volksgezondheid en Milieu * National Institute for Public Health and the Environment (Netherlands)
- SP. Sanofi Pasteur (France)
- SP MSD. Sanofi Pasteur MSD (France)
- SSI. Statens Serum Institut (Denmark)
- SURREY. The University of Surrey (United Kingdom)
- SYNAPSE. Synapse Research Management Partners, S.L. (Spain)
- TAKEDA. Takeda Pharmaceuticals International GmbH (Switzerland)
- UNIBAS. Universitàet Basel (Switzerland) - Managing entity of the IMI JU funding
- UTA. Tampereen Yliopisto (Finland)
- WIV-ISP. Institut Scientifique de Santé Publique (Belgium)

- Grant Agreement. The agreement signed between the beneficiaries and the IMI JU for the undertaking of the ADVANCE project (115557).
- Project. The sum of all activities carried out in the framework of the Grant Agreement.
- Work plan. Schedule of tasks, deliverables, efforts, dates and responsibilities corresponding to the work to be carried out, as specified in Annex I to the Grant Agreement.
- Consortium. The ADVANCE Consortium, comprising the above-mentioned legal entities.
- Project Agreement. Agreement concluded amongst ADVANCE participants for the implementation of the Grant Agreement. Such an agreement shall not affect the parties’ obligations to the Community and/or to one another arising from the Grant Agreement.

List of abbreviations:
Good Practice Guidance - Module 2: Governance models

WP1. Best practice and code of conduct for benefit-risk monitoring vaccines

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- CRO: Contract Research Organisation
- EC: European commission
- ENCePP: European Network of Centers for Pharmacoepidemiology and Pharmacovigilance
- EU: European Union
- PoC: Proof of Concept
- SME: Small and Medium Size Entreprise
EXECUTIVE SUMMARY

Enabling successful cooperation between stakeholders through appropriate governance are among the main objectives of ADVANCE. This document should be considered as an intermediate step towards the final deliverable which will recommend governance model(s) for future implementations of collaborations or partnerships on vaccine benefit-risk monitoring in Europe. This preliminary work defines a governance framework and develops potential relevant models for public-private interactions in post-ADVANCE area.

The development of this document is based on an analysis of the current practice of the public-private interactions, completed by the investigation of some well-known and transparent structures. The governance proposal is built around five key functions: decision making, technical/scientific advisory, implementation/management, quality control/audit and finance. A clear distinction is made between collaborations and partnerships. In collaborations, decision-making is endorsed by a single responsible party. In partnerships, decision-making is shared between stakeholders.

To support the implementation of such governance, four typologies of models together with general guiding principles are presented as potentially relevant for the post-ADVANCE area.
1. INTRODUCTION

To address limitations in the current capacity for conducting rapid vaccine benefit-risk monitoring activities, the ADVANCE project was initiated with the vision to deliver best evidence at the right time to support decision-making in Europe. Its mission is to establish a validated and tested best practice framework to rapidly provide robust data on vaccine benefits and risks to support accelerated decision making throughout the life cycle of vaccines. For this purpose, it should fulfil the needs of different stakeholders (e.g. national authorities, insurance companies, regulatory agencies, public health agencies, vaccine manufacturers, health care providers, consumers, etc).

Fruitful collaboration between stakeholders and governance for the conduct of studies are among the main objectives of ADVANCE. In this context, Work Package 1 will develop a good practice guidance including core values to be integrated in this framework, interaction models, and principles of governance between public and private stakeholders that might be utilised to build a platform to conduct sustainable, transparent and high quality vaccine performance studies. Supported by a relevant communication strategy, these initiatives should enhance the trust in vaccination and in immunisation programmes.

The good practice guidance (GPG) is divided into four modules covering different aspects:
- Module 1: Code of Conduct
- Module 2: Governance models
- Module 3: Quality management
- Module 4: Communication recommendations.

This Deliverable 1.5 is part of Module 2 and is an intermediate step towards deliverable 1.10 "Final conceptual model for public-private interaction". By the end of the ADVANCE project, one of the final objectives will be to propose governance model(s) as recommendations for future implementations of collaborations or partnerships on vaccine benefit-risk monitoring in Europe.

This document is a preliminary work aiming to build a governance structure to be tested in PoC studies and to develop potential related models of public-private interactions for the post-ADVANCE area.

2. METHODS

The development of this document was based on two sources of information:

- A landscape analysis of the existing collaborations and partnerships in public health for an overview of the current practices. Its objective was to identify models which may be of interest for the ADVANCE framework. A survey was conducted within ADVANCE partners
with ENCePP centres collaboration to gather information on private-public initiatives through a questionnaire. A literature search was done in Pubmed to identify the additional models which may not be captured in the survey. Information on 70 collaborations and partnerships were collected: thirty-eight (54.3%) were between private and public stakeholders and thirty-two (45.7%) between solely public stakeholders. Through the survey’ questionnaires, structure and governance of the most current and successful initiatives were investigated as a basis for the development of conceptual models. The results of this survey were presented in Deliverable 1.3 “Final report on existing models of public-private interactions”.

- An investigation of some well-known governance structures and guiding documents which could support us for the elaboration of principles. References and guidance’s about governance models which may be relevant and applicable for the ADVANCE framework are quite limited. General principles were elaborated based on validated models of PPP such as The Global Fund for the fight against HIV, tuberculosis and malaria or GAVI. The definition of the role and the added value of the private sector in such models was also inspired by a general review of PPP models (Public Private partnerships: Assessing the private sector’s unique ability to enhance social impact. McKinsey & Compagny, 2009).

3. DEFINITIONS

Although a study may be entirely conducted within a single institution, it has been assumed in ADVANCE that large vaccine B/R studies will generally benefit from the involvement of several different European stakeholders already involved in related efforts.

3.1. Types of institutional roles

Three types of institutional role can be defined according to the level of study responsibility.

- **Responsible party**: An organisation having responsibility and accountability for all aspects of the conduct of the studies. The responsible party may allocate the activities associated to its roles to a Steering Committee and/or a Study team. It may subcontract or delegate some of the study activities to other entities. The term of “sponsor” is also sometime used.

- **Contributors**: An organisation contributing to any aspect of the conduct of the study. It may include the implementation, data provision, data analysis, etc.

- **Trustee**: An organisation solely responsible of the management and channelling of the funds devoted to the project.

3.2. Types of interactions

In this module, we focus on interactions between stakeholders who work together to ensure the conduct of quality studies. Contractual relationships based on service provision are excluded from the interaction models we are focusing on. However, it is understood that some
for the roles or activities within the considered interactions can be subcontracted to a service provider.

Two types of interaction can be defined:

- **Collaboration**: A collaboration is an arrangement between stakeholders having a joint interest to act together in a project. The legal responsibility of the project is endorsed by a single party. Roles are distributed between parties. Because collaborations have usually a very specific scope (e.g. conduct of a study), they are usually time limited.

- **Partnership**: A partnership is an arrangement between several stakeholders having a common vision/mission and shared goals. A governance structure is created to establish shared decision-making. All partners have the right and the responsibility to participate and will be affected by the benefits and other consequences arising from the partnership. The responsibility of the project is legally endorsed by all governance partners. Roles, resources and/or financial investments are shared between parties. Partnership structures are more complicated to set up and they are usually used for longer terms initiatives with broader objectives including the management of an array of studies.

### 3.3. Types of stakeholders

While conflicts of interest can be of various natures, the most obvious ones are probably those linked to commercial interests. Four types of stakeholders can be distinguished depending on the related susceptibility for commercial conflict of interests (whether it is real or perceived) in vaccine benefit/risk evaluation (rated from low to high).

- **Public**: Organisations that are owned and operated by the government including public body and public authority. It includes:
  - Regulatory agencies (overseeing overall adherence to the regulatory framework)
  - Public Health Institutes (providing support for public health policy through scientific research, surveillance, scientific advice, risk assessment, etc)
  - Public or state Universities (providing education and conducting research)

- **Private**: Organisations that are privately owned including for profit and non-for-profit structures. Several categories can be distinguished:
  - **Private non for profit**: Organisations that do not earn profits for its owners and uses surplus revenues to achieve its goals rather than distributing them as profit or dividends. It includes Research institutions and private universities, foundations, associations (e.g. professional societies, patients associations …).
  - **Private for profit**: Organisations that aim to earn profit through its operations. It includes Contract Research Organisation (CRO) and Small and Medium Enterprises (SME);
  - **Vaccine manufacturers**: private for profit companies that are regulated by authorities for vaccines development, production and/or distribution and that generate commercial benefit directly through the sales of vaccines.
4. STRUCTURE, ORGANISATION AND PRINCIPLES OF GOVERNANCE

4.1. Structure and organisation

Any collaboration or partnership needs to establish a structure of governance. It allows to further define role and responsibilities of stakeholders in addition to defining the goals and objectives that should be met to achieve the vision and mission and to articulating the organisation, its owners and the policies that derive from these values.

Our proposal of governance structure is articulated around 5 key functions (Figure 1). These functions are framed in the context of a broader initiative/project that may include several types of stakeholders and several studies. Depending on the model of interaction chosen, these functions can be distributed between stakeholders (collaborative model) or incarnated by a specific body/committee who will endorse the joint mandate of the partners (partnership model).

**Figure 1. Governance structure diagram by functions**

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This function is responsible for the overall governance, including strategic direction, decisions on funding and resource allocation. This function endorses more specifically the following roles and responsibilities:

- Set the strategic vision and mission;
- Define the roles and responsibilities of the parties, constituting the appropriate committees, selecting the appropriate persons; ensuring that all functions and tasks are assigned for the project;
- Govern the overall project, endorsing the work plan, following up high-level progress in each of the critical areas of the project; taking when necessary the appropriate corrective actions and performing contingency plan and risk management for the project;
- Allocate and reassign if necessary budget and resources to projects aligned with the vision and mission;
- Seek advice from other parties or committees for technical, scientific, quality and compliance considerations;
- Endorse the project deliverables, ensuring that objectives and milestones are fulfilled with an appropriate quality level;
- Manage external communication and advocacy related to the collaboration/partnership;
- Ensure study results are published and communicated

**Technical/scientific advisory**

This function is responsible for the scientific advisory aspect of the project. This function endorses more specifically the following roles/responsibilities:

- Contribute to, review and validate scientific related deliverables such as research plan, protocol, analysis, interpretations, report, scientific communication and publication;
- Advises the party or committee in charge of the decision making

**Implementation/Management**

This function is responsible for the implementation and the conduct of the project(s) under oversight of the decision making function. This function ensures technical, legal and administrative due diligence to meet the project timelines and milestones. This function can be restricted to implementation oversight in the case of large projects where data collection is subcontracted to other institutions.

This function endorses more specifically the following roles/responsibilities:

- Manage the day-to-day operational aspects of the project, ensuring technical, legal (e.g. contracts development) and administrative (e.g. ethics and data protection related submission) due diligence and liaising with the project stakeholders as required;
- Ensure or subcontract actual data collection and studies performance;
- Ensure that all persons involved in the project implementation are well informed and qualified and organise appropriate trainings when needed;
- Report progress to the party or committee in charge of the decision making and suggest eventual corrective actions (e.g. modification of the protocol); Produce the scientific related deliverables such as research plan, protocol, analysis, interpretations, report, scientific communication and publication and organise their endorsement by the technical/scientific advisory function;

**Quality control and audit**
This function is responsible for the overall quality and transparency of the project ensuring the ethic, compliance and quality of the project. This function endorses more specifically the following roles/responsibilities:

- Ensure the compliance of the project to the appropriate guidelines, national and international standards as well as the ADVANCE code of conduct including the control of the ethical and legal aspects of the project.
- Monitor compliance of data processing with applicable national and international standards of data security and data protection.
- Ensure the transparency of the funding flow when applicable.
- Check the potential conflicts of interests which may occur in the project and make sure proper declarations are recorded; escalate any related issues to the party or committee in charge of the decision making.
- Provide oversight for eventual external evaluations related to the collaboration/partnership governance or to specific projects on behalf of the decision making function.
- Report regularly findings to the party or committee in charge of the decision making.

**Finance**

This function is responsible for the management of the funds devoted to the project. This function endorses more specifically the following roles/responsibilities:

- Manage the budget to ensure financial transparency and supporting independency.
- Report on traceability of the source and beneficiary of funds to the party or committee in charge of the decision making.

In the context of initiatives like the monitoring of vaccine benefit-risk in Europe which includes strong scientific components, the technical/scientific advisory function may be either merged with the decision making function (for a more scientifically oriented decision making) or with the implementation/management function (for an additional external scientific input). In this governance structure, only the decision-making function cannot be outsourced as it represents the "raison d’être" and the legal incarnation of the multi-stakeholders initiative. The other functions (Technical/scientific advisory, Implementation/Management, Quality control & audit, and Finance) can be commissioned to one or several entities provided they can adequately fulfill the roles and responsibilities corresponding to that function and provided they are given sufficient oversight.

“Third party” is a term often used to designate an external entity (person or organisation) with a different role than the one of the two parties involved in a collaboration/partnership. In such case, a third party may perform different tasks that require an intermediate structure between stakeholders, for example to receive funds from a private entity and channel it to public entity, or to perform linkages between data sources. The third-party is often a CRO-SME, an academia or a foundation. In the governance structure we described, the term “third party” is not used since it needs to be fully integrated in the governance structure and assigned a precise and transparent role. The “third party” should not be involved in decision making and it should not cumulate several non-compatible functions.
4.2. Guiding principles

The creation and structure of a collaboration or partnership for monitoring B/R of vaccines should be guided by the interest of public health through better scientific evidence, along with appropriate transparency.

In addition to the general principles described in the Code of Conduct, governance related principles can be stressed for the implementation of collaborations and partnerships for vaccine benefit-risk monitoring in Europe:

- Keep it simple, lean and pragmatic
- Allocate clear role and responsibilities and decision making rules upfront – do not leave room for interpretation
- Ensure balance of the decision making between responsible parties
- Ensure role and responsibilities are full of people with relevant skills
- Maximise transparency by documenting all decisions and contributions

This is in line with other recommendations on PPP for public health:

"Relationship should always have specific aims and meet the following criteria:
- the relationship should contribute to improving public health
- the public health gains should be commensurate with the time and expense to establish and maintain the relationship
- relationship should be established on the basis of clear agreement (...)"
WHO Guidelines on working with the private sector to achieve health outcomes, Nov 2000

"The general principles of partnership building are established on the basis of mutual respect, transparency, and shared benefit. All corporate partnership should contribute clear health gains"
APUA Guidelines on interaction with commercial enterprises, March 2000

Based on these principles, the following guidance can be provided:

- Formal multi-stakeholder initiatives are demanding and time intensive. Careful judgement whatever collaboration or partnership is the best form of interactions should be considered; a clear understanding of why the partners are coming together and why their objectives cannot be achieved through easier mechanisms should be addressed at the earliest stage; the common interest of the stakeholders, the project objectives and the vision of the initiative should be clearly stated and agreed.

- Irrespective of the chosen model of interaction, the structure of governance should be kept simple and appropriately sized to ensure efficiency. A committee should be set up only when several representatives are needed to fulfil a specific function.

- Agreement should be established between parties to formalize terms and conditions of the interaction. Roles and responsibilities of the parties and governance structure should be discussed and agreed at the beginning and stated in the agreement/Memorandum of Understanding including the contribution in terms of resources, expertise and capabilities to achieve objectives
• All decisions, key communications and meetings minutes should be documented (with proper identification of each stakeholder contribution) and made public to ensure the transparency of the governance and to prevent suspicion of conflicts of interests. For example, an inclusion of representatives from patients of HCP association as observers in the decision making function could also support this effort of transparency.

• The skills and competencies of any representative in a governance body should be in line with his/her function within the governance structure (for example: only representative with scientific expertise are eligible for technical advisory function).

• All functions/mandates should not be cumulated by a same institution. In particular, some functions should not be cumulated such as: (i) implementation and auditing (to ensure independence of the auditing process); (ii) implementation/technical advisory and finance (to prevent real or perceived conflicts of interests).

• Governance processes and decisions should focus on what is best to achieve the objectives of the partnership rather than seeking compromise between the interests of different stakeholders; these processes should welcome a variety of inputs but should not require full consensus on the final decision which has to be made in a timely manner. The different perspectives of the stakeholders should nevertheless be considered as a value of the partnership and governance structure should ensure that all stakeholders’ views can be heard.

5. POTENTIAL RELEVANT MODELS OF GOVERNANCE

This chapter describes and illustrates four models of governance with various levels of complexity and degrees of involvement of stakeholders. It shows how the distribution of the key functions among the different parties.

None of these four models of interactions are considered superior to the others as the choice of model may depend on the nature of the study itself, the number of partners involved, the relationships between partners and how the partners’ vision of how they should or could collaborate with each other to answer a research question. However, the ADVANCE consortium recommends that partners consider these four models whenever they enter into discussions to conduct a study or a set of studies and choose which one will be followed in order to facilitate the discussions, explicit the type of interactions agreed between them, gain time by avoiding potentially lengthy negotiations about the allocation of tasks and clarify roles and responsibilities. In such discussions, the choice to adopt (or not) the ADVANCE Code of Conduct should also be addressed.

Section 5.2 presents real-life examples illustrating implicit choices of interactions adopted by the partners involved. This list of examples will be expanded at a later stage.
**Legend for the following models**

Parties are defined based on their institutional roles (in black fonts). Parties mentioned in a box with solid lines are essential, those mentioned in a box with dotted lines are optional. The governance functions are indicated in red fonts. Bodies required for the governance are indicated in white fonts.

### 5.1. Models

**Model 1: Public-private collaboration**

- **Responsible party**
  - Decision making
  - Quality control & Audit

- **Contributor**
  - Technical/Scientific Advisory
  - Implementation/management

- **Trustee**
  - Finance

For the evaluation of the benefit risk of vaccine, the direct contribution from public health institutions in the implementation is usually necessary (since they are overseeing immunisation programs). These institutions are contributors by being in charge of the implementation (or its oversight) and through their strong scientific and technical expertise. The ultimate responsibility of the project usually lies with the responsible party. Data ownership can be shared between the responsible party and the contributor.

In this model, the responsible party does not contribute to the results generation but is allowed to make non-binding comments on the results and/or their interpretation for the contributor consideration (this differs from a service provision).

**Role of the trustee**

In this type of collaboration, a trustee is not essential but can be used to manage the financial assets. This is particularly useful when funding is coming from several sources or in different
In the most current practices (referring to the collaborations captured through the landscape analysis), scientific committees are set up and added to the previous model. These committees include representatives from the contributor(s), responsible party and often other external experts (from academics or public health authorities). These committees advise on the scientific conduct of the project. They are considered as a guarantee of the scientific independence for the project in private-public collaborations.

Often, these collaborations are perceived as “partnership” since the scientific input is based on consensus between representatives from the various stakeholders. However, this should not be qualified as such since there is neither joint decision making nor shared funding.
Model 3: Basic public private partnership

When a joint undertaking between the vaccine manufacturers and the public sector is needed, a partnership model with share decision making is necessary. All decisions are made by a body including representatives from both funding stakeholders. In the simplest model, this body usually also cumulates the technical/scientific advisory and the quality control/audit mandates. All partners are co-responsible of the joint initiative/project, co-owner of the data and co-responsible of the deliverables. Implementation is performed or overseen by a contributor which can be either a CRO/SME or a public institution funded by a trustee who manage budget coming from both public and private sectors.
Model 4: Comprehensive public private partnership

For more comprehensive and/or more demanding partnership models, the steering committee cannot fulfill all the mandates because of time and competencies. In this case, the scientific and audit mandates are allocated to two additional committees who report to the steering committee. These committees can be formed of members of the partner’s institutions (balanced representation) and external expert/qualified persons.
5.2. Examples

ADVANCE

The current IMI ADVANCE partnership follows the partnership model 4. All stakeholders (public and private (EFPIA) stakeholders) have shared responsibilities and decisions making through representation in the steering committee. The trustee is the European Commission which provides the funding through the IMI mechanism. Administrative management of the project is subcontracted to a CRO (synapse) but the technical implementation are done by the Coordination team and the co-leaders of the five work packages which include representatives from the various stakeholders of the projects. Scientific advisory is done by independent experts external to the project. The steering committee endorse the function of the quality control and audit.

I-MOVE

The I-MOVE in Europe (Influenza - Monitoring Vaccine Effectiveness) project aims at measuring influenza vaccine effectiveness in Europe. The project started in 2007. In the first four seasons of I-MOVE (2008-9 to 2011-12) the European Centre for Disease Prevention and Control (ECDC) and countries conducting studies co-funded the project. I-MOVE corresponds to the collaborative model 2 without trustee. The funding and oversight is provided by ECDC (the responsible party). The CRO Epiconcept is the contributor. Epiconcept allocates the funding from the ECDC and oversees the implementation of the national studies performed by public health institutes. Public health institutes are owner of the data they generate but a yearly pooled analysis is performed by Epiconcept. As part of the scientific committee, public health institutes, few external experts and ECDC are invited to a yearly meeting where results are presented and discussed.

6. CONCLUSION

This document is an intermediate step towards the final deliverable which will propose governance model(s) as recommendations for future implementations of collaborations or partnerships on vaccine benefit-risk monitoring in Europe. This preliminary work aims to build a consensus on a comprehensive and relevant governance structure framework supported by some guiding principles and on potential models of governance for post-ADVANCE area.

The next steps will be to further investigate the role of the different stakeholders within the models of governance especially in relation to commercial conflicts of interest, to ask for a public consultation and to incorporate related lessons learnt following the conduction of the PoC studies.