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**Accelerated Development of VAccine beNefit-risk
Collaboration in Europe**

Grant Agreement n°115557

**D7.4 Compilation from WP7 of
recommendations on key deliverables
made during year 4**

WP7 – Implementability analysis

Final

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REPORT OF REVIEW PANEL 3 ON THE IMPLEMENTABILITY OF THE ADVANCE PROJECT DELIVERABLE 3.5: “WHITE PAPER: PROCEDURES FOR DATA ACCESS, SHARING, LINKAGE AND INTEGRATION, INCLUDING PRIVACY AND ETHICS”

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DOCUMENT INFORMATION

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Description of the deliverable	This is a compilation of WP7's and external Review Panels' recommendations made during year four on key reviewed ADVANCE deliverables
Key words	Review panel, implementability


DOCUMENT HISTORY

NAME	DATE	VERSION	DESCRIPTION
David Young	06/11/2017	1.0	First draft
Piotr Kramarz	09/11/2017	1.1	Internal review
Piotr Kramarz	15/12/2017	1.2	Final version after feedback from SC

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DEFINITIONS

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

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▪ **Abbreviations**

- **ADVANCE** Accelerated development of vaccine benefit-risk collaboration in Europe
- **D** Deliverable (e.g. D1.9 indicates the ninth deliverable from Work Package 1)
- **DoW** Description of Work
- **EEA** European Economic Area
- **RP** Review Panel
- **WP** Work Package

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EXECUTIVE SUMMARY¹


The goal of the ADVANCE ('Accelerated development of vaccine benefit-risk collaboration in Europe') project is to help professionals, regulatory agencies, public health institutions, vaccine manufacturers and the general public to make more informed decisions on the benefits and risks of marketed vaccines.

To assess the implementability of solutions proposed by ADVANCE, ECDC seeks input from external experts, who form so-called Review Panels. Each panel reviews the key deliverables from one of the five technical Work Packages of ADVANCE. 'Implementability' here is defined as real-life feasibility for EU-level vaccine benefit/risk assessment, and usefulness in meeting the requirements of various stakeholders and potential users (e.g. national and EU/EEA regulatory agencies, national and EU/EEA public health agencies, vaccine manufacturers, healthcare providers, health consumers and others).

Under ECDC coordination, the Review Panel members establish evaluation criteria, assess key deliverables, meet face-to-face or by teleconference and provide comments to the ADVANCE project Steering Committee in the form of a written report. In order to track the work of Work Package 7 and its Review Panels, ECDC is to produce annual compilations of recommendations made during the project year on key deliverables. This report (Deliverable 7.4) compiles recommendations made during the fourth project year (1 October 2016 to 30 September 2017).

The attached Review Panel reports (including summary tables of recommendations made) contain a wide range of valuable suggestions on governance, public-private interaction, data access, methodology for assessing benefits and risks, and many other areas that will be of direct relevance for drafting the final Blueprint and developing the vision for a rapid, integrated benefit-risk framework.

¹ Maximum 2,000 characters (including spaces)

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1. Introduction

1.1. ADVANCE project and ECDC internal project organisation


At the European Centre for Disease Prevention and Control (ECDC) the project is managed by an internal team of experts responsible for organising Review Panels (RPs) for particular Work Packages (WPs) and assisting RP members in their review of key deliverables. Table 1 lists the internal team of experts (reflecting changes made during year two of the project).

Table 1: List of ECDC internal team members in charge of organizing RPs for specific WPs

Responsibility for	Position	Name
Member of the ADVANCE Steering Committee	Senior Advisor to ECDC Director	Maarit Kokki
Internal ADVANCE project lead WP7 - Implementability analysis	Deputy Chief Scientist/Head of Section Disease Programmes	Piotr Kramarz
WP1 - Best practice and code of conduct for benefit-risk monitoring of vaccines	Senior Expert Vaccine-preventable Diseases	Tarik Derrough
WP2 - Creation of synergies for benefit-risk monitoring in Europe	Head of Disease Programme Vaccine-preventable Diseases	Lucia Pastore Celentano
WP3 - Data sources for rapid and integrated benefit-risk monitoring	Senior Expert Data Management/Group Leader Surveillance Data Services	Gaetan Guyodo
WP4 - Methods for burden of disease, vaccination coverage, vaccine safety & effectiveness, impact and benefit-risk monitoring	Expert Science-based Prevention & Guidance for Infectious Diseases	Edoardo Colzani
WP5 - Proof-of-concept studies of a framework to perform vaccine benefit-risk monitoring	Expert Vaccine-preventable Diseases	Kari Johansen

1.2. Objectives and plans of Work Package 7

The main objective of WP7 is to create a blueprint that will describe a validated and tested best practice framework for vaccine benefit-risk monitoring in Europe. WP7 is led by ECDC and focuses on assessing the 'implementability' of the solutions proposed by five other technical WPs of the project.

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'Implementability' is defined here as real life feasibility of solutions proposed for EU-level vaccine benefit/risk assessment and their usefulness in meeting the requirements of various stakeholders/potential users (e.g. national and EU/EEA regulatory agencies, national and EU/EEA public health agencies, vaccine manufacturers, healthcare providers, health consumers and others).

As described in the DoW, in order to track the work of WP7 and its RPs, annual compilations of recommendations on key deliverables made during the project year should be produced as part of WP7's deliverables. This is the fourth such scheduled compilation (i.e. Deliverable 7.4).² Table 2 lists the key deliverables due from WP7, with deadlines from the latest DoW (October 2017). Table 3 provides an updated list of deliverables meant for review by RPs (taking account of revised deadlines as agreed by the Steering Committee).

Table 2: WP7's key deliverables

Deliverable no.	Deliverable name	Delivery date	Deadline
7.1	Compilation from WP7 of recommendations made during the year on key deliverables no. 1	Month 15	31/12/14
7.2	Compilation from WP7 of recommendations made during the year on key deliverables no. 2	Month 28	31/1/16
7.3	Compilation from WP7 of recommendations made during the year on key deliverables no. 3	Month 41	28/2/17
7.4	Compilation from WP7 of recommendations made during the year on key deliverables no. 4	Month 51	31/12/17
7.5	Draft blueprint for public consultation	Month 57	31/5/18
7.6	Summary report of public consultation	Month 58	30/6/18
7.7	Final blueprint	Month 60	30/9/18

² The planned deliverables 7.2 and 7.3 were redundant since no further review panel reports were produced during the second and third project years. Recommendations from the report of RP2 on D2.2 were compiled in D7.1 even though the date of the final RP2 report (31/10/14) fell within the second project year.


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Table 3: Key deliverables of other technical WPs to be reviewed by the RPs


Deliverable no.	Deliverable name	Delivery date	Deadline	Received
5.1	Report on available IT platform	Month 7	30/4/14	23/4/14
2.2	Utilization strategy of outputs from other initiatives	Month 10	31/7/14	31/7/14
1.9	Guidance on best practice final	Month 36	30/9/16	14/10/16
1.10	Final conceptual model for public-private interaction	Month 36	30/9/16	17/10/16
3.5	White paper regarding procedures for data access, sharing, linkage and integration, including privacy and ethics	Month 42	31/3/17	31/3/17
4.9	White paper (recommendations) of WP4 for the final blueprint (WP7)	Month 44	31/5/17	31/5/17
5.6	Results of Mock-up/ POC studies Phase 1	Month 46	31/7/17	27/7/17
1.12	Strategy for public communication in the context of vaccine benefit-risk monitoring	Month 48	30/9/17	4/10/17
1.13	White paper (recommendations) of WP1 for the final blueprint (WP7)	Month 48	30/9/17	29/9/17
5.7*	Results of Mock-up/ POC studies Phase 2	Month 50	30/11/17	
5.9*	White paper (recommendations) of WP5 for the final blueprint (WP7)	Month 50	30/11/17	

Notes: Revised deadlines according to the latest Description of Work (October 2017). *Subject to agreement by IMI, the Steering Committee has proposed to shelve the reviews of Deliverables 5.7 and 5.9 since this work would overlap with the work of the Implementability Advisory Board (on which panel members will also sit).

2. ECDC work during the fourth project year

Between 1 October 2016 and 30 September 2017, ECDC organised review processes for the following key deliverables:

- D1.9 'Guidance on best practice final – Modules 1 and 3: Code of Conduct and Quality recommendations' and D1.10 'Final conceptual models for public-private interaction' (Review Panel 1 report, 18 January 2017)

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- D3.5 'White paper: procedures for data access, sharing, linkage and integration, including privacy and ethics' (Review Panel 3 report, 30 June 2017)
- D4.9 'White Paper: methods for vaccine benefit-risk monitoring, including vaccine coverage, safety and effectiveness' (Review Panel 4 report, 31 August 2017)
- D5.6 'Results of POC-phase 1 studies' (Review Panel 5 report, 27 October 2017).


In addition, ECDC commenced the review process for D1.12 'Strategy for public communication in the context of vaccine benefit-risk monitoring' and D1.13 'White paper (recommendations) of WP1 for the final Blueprint' (Review Panel 1 report due by the end of December 2017).

Composition of the RPs, selection of panel members and working methods were as specified in the DoW and in the attached RP reports. Each report provides a list of panel members, further details on composition and selection procedures, and an outline of working methods (including dates of teleconferences, face-to-face meetings and draft reports). For a detailed summary of evaluation criteria, evaluation results and suggestions to the ADVANCE Steering Committee, readers are referred to the table at the end of each of the reports in annex.

To summarise the process in brief:

- RPs are composed of stakeholder and user representatives from the following groups: EU/EEA Ministries of Health, National Public Health Institutes, National Regulatory Agencies, World Health Organization, Vaccines Europe, representatives/custodians of relevant immunisation registries and healthcare outcome databases, data protection supervisors, professional societies representing healthcare workers and public health professionals and patient organisations.
- Before receiving the deliverables for review, panel members were asked to consider and propose criteria for evaluating implementability from their stakeholder or user perspective. They were then invited to evaluate deliverables based on these criteria, and to provide suggestions for the ADVANCE Steering Committee.
- A kick-off teleconference was held for each panel to explain the process, and each panel met at least once face-to-face (at ECDC's premises in Stockholm) to discuss their evaluation and the contents of the panel's report. In cases where the panel had already met previously (RP5), this evaluation meeting was conducted by teleconference. Further teleconferences were held where necessary.
- On the basis of these discussions and panel members' written input, ECDC prepared a draft 'evaluation table' of criteria, evaluation and suggestions and circulated this to panel members for further discussion and feedback. These evaluation tables form the core substance of the RP reports, full drafts of which were then circulated to members for final comments. Panel members were generally able to agree on a common report, with the exception of RP1's report on D1.9 and D1.10, where the positions of the different stakeholders are indicated in the summary table.

While the RPs' work covers a wide range of subjects, taken together the attached reports confirm the relevance of ADVANCE for stakeholders and users. Panel members have commended the impressive body of work that the project has produced, while at the same time highlighting the improvements that will be necessary to facilitate real-world application by different stakeholders in different countries. The attached reports contain a wide range of useful suggestions on governance, public-private interaction,

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data access, methodology for assessing benefits and risks, and many other areas that will be of direct relevance for drafting the final Blueprint. As panel members now go on to form the Implementability Advisory Board, their familiarity with ADVANCE and its relevance to users and stakeholders will continue to be invaluable in developing the vision for a rapid, integrated benefit-risk framework.