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Accelerated Development of VAccine beNefit-risk Collaboration in Europe

Grant Agreement n°115557

D6.9 Report on activities implemented supporting internal communication, knowledge management and training

WP6 – Project management and communication

**V2.0
[Final]**

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	WP6. Project management and communication		Version: v2.0 – Final
	Author(s): Antonella Chiucchiuini, Eva Molero, Natasha Yefimenko		Security: Public

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DOCUMENT INFORMATION

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Authors (Partner)	Takeda / SYNAPSE			
Responsible Author	Antonella Chiucchiuini	Email	Antonella.Chiucchiuini@takeda.com	
	Partner	Takeda	Phone	
	Eva Molero, Natasha Yefimenko	Email	emolero@synapse-managers.com	
	Partner	SYNAPSE	Phone	+34 93 300 60 61

Description of the deliverable	A detailed list of communication, knowledge management and training tools and activities implemented by the project.
Key words	Sharepoint, Bulletin, Webinars, SharePoint, Flyer

DOCUMENT HISTORY¹

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Eva Molero	12.04.2019	1.2	Updated draft
Antonella Chiucchiuini	15.04.2019	1.2	Updated draft
	17.04.2019	1.3	Review and changes
		1.4	Review and comments
		2.0	Final version

¹ The name of all reviewers of the document should be included in the table

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DEFINITIONS²

- Participants of the ADVANCE Consortium are referred to herein according to the following codes:
 - **P95.** P95 (Belgium), 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)
 - **EMC.** Erasmus Universitair Medisch Centrum Rotterdam (Netherlands)
 - **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)
 - **SCIENSANO.** 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)*
 - **MSD.** Merck Sharp & Dohme (France)
 - **JANSSEN.** Janssen Vaccines & Prevention B.V. (Netherlands)
 - **PFIZER.** Pfizer Limited (United Kingdom)
 - **TAKEDA.** Takeda Pharmaceuticals International Ag (Switzerland)
 - **ARS Toscana** - Agenzia Regionale di Sanità, Toscana (Italy)
 - **IDIAP JORDI GOL.** Fundació Institut Universitari per a la Recerca a l'Atenció Primària de Salut Jordi Gol i Gurina (Spain)

** Effective 9 November 2015, bioCSL, the vaccine and pharmaceutical business of CSL, acquired the influenza vaccines business of Novartis, to create Seqirus, a CSL company. Seqirus and Novartis operate at interim under the Sale and Purchase Agreement governing the sale to CSL as well as the relevant TSAs and TDSA.*

- **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.

² To be completed with terms and abbreviations related to the actual content of the document

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EXECUTIVE SUMMARY³

The present document aims at describing the internal communication, knowledge management and training tools and activities conducted during the ADVANCE project to keep the partners updated about the status of project activities and outcomes.

The following activities are addressed in the report: newsletter and bulletin, flyer, Share Point collaborative space, distribution lists, meetings and workshops, teleconferences.

The activities were planned taking into account the D6.3 Communication Plan & Initial tool set.

³ Maximum 2,000 characters (including spaces)

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1. Introduction

The ADVANCE consortium constituted by 40 public partners including public health institutes and regulatory bodies, 7 vaccine manufacturers and 19 associated partners has required careful planning, implementation, management and monitoring of the internal communication and knowledge management activities in order to promote synergies, avoid controversies and misunderstanding, to ensure a transparent governance of the activities and to strengthen the cooperation.

The main result of this effort has been the generation of a working environment where both public and private bodies could cooperate comfortably, ensuring that everyone had sufficient information about ADVANCE at the right time.

WP6 leaders and the coordinating team monitored the internal communication activities regularly and took prompt action in case of specific requests from the partners.

As it was described in the D6.3 Communication Plan & Initial tool set, at the beginning of the project, it was decided to implement a Share Point site to archive all the relevant material related to the various project activities: documents, results, procedures, protocols etc. All the partners and associated partners were given access to Share Point and could upload files in the folders related to their main activities.


The ADVANCE Share Point is hosted by partner Sciensano will remain active for 5 years after the end of the project.

Almost 50 ADVANCE distribution lists created since the beginning of the project have been updated regularly and frequently used by the Coordination Team members and by the WP Leaders to inform the project partners and to work together on specific topics.

To guarantee the continuous flow of information, regular teleconferences or web meeting have been organised: weekly for the Coordination Team, monthly for the Steering Committee, on demand for each WPs.

In addition, a General Assembly face-to-face meetings were organised twice/year to facilitate direct interaction and discussions among the partners and associate partners. The General Assembly meetings were joined by members of the Scientific Advisory Board once per year. Details on such meetings have been extensively reported in the periodic reports and the final report of the project. The SC had also multiple face to face meetings, typically every quarter, to align on strategic matters (vision and mission of ADVANCE, selection of POC studies, approach for White Papers, etc.). Noteworthy is the SC Bootcamp that was held in January 2018 to align on sustainability matters regarding the post-ADVANCE phase.

The internal Newsletter was substituted from the third year by a Bulletin having a nicer layout considered more adequate to deliver the information to the project partners. The bulletin was

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circulated any time there was a need to provide an update to the consortium, for special announcement and to inform about major news and outcomes.

The bulletins have also been used to inform about webinars organised to provide training on the tools developed by the project and to inform about some of the major ADVANCE outcomes (e.g. Governance models etc).

During the last year there was no longer need of newsletters or bulletins as the project coordinator, the coordinating team and the WP leaders had intensified the already frequent interactions by email or by web conferences with the other partners in order to complete all the pending activities on time before the end of the project.

The project partners and associated partners used mainly the emails to reach out the management bodies, either directly or through the WP leaders.

The EFPIA companies organized monthly web meeting to deal with issues more specific for the industrial partners, e.g. to monitor the use of the contribution in kind and to get aligned in order to facilitate the communication and interactions with the other project partners.

The structure of the management team allowed an optimal circulation of the information thanks to the pyramidal structure, from the coordinating team to the project partners through the SC composed by the WP leaders and co-leaders, and vice-versa.

2. Communication and dissemination tools

2.1 Bulletin

In total eight Bulletins were issued (February 2016, March 2016 (2x), December 2016, March 2017, July 2017, December 2017(2x)) to update the whole consortium, including associated partners on the ongoing activities within the work packages as well as major project outcomes, publications, action points and webinars.


A screenshot of the bulletins is provided in the Annex 1.

The bulletins were sent through the easily recognizable email address: bulletin@advance-vaccines.eu; monitoring on the reading was possible.

2.2 Flyer

In order to provide consolidated information on ADVANCE and on the outcomes and sustainability plan to the project partners to share internally, in their institutions, and externally to key stakeholders, the SC decided to prepare a flyer structured as it follows:

- What is ADVANCE (high level overview of the project)
- How did we ADVANCE (procedures and methods)?
 - Environment & readiness (best practices, code of conduct and governance)
 - Data source readiness (data sources assessment and model for multi-database studies)

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- Methods readiness (methods and tools)
- Study readiness (best practice)
- Implementation plan (blueprint and plan for the VAC4EU association)
- Acknowledgment (IMI)
- ADVANCE partners (list)
- ADVANCE associated partners (list)

The content was prepared by the CT, revised by the SC and the project partners and by Vital Transformation. A professional graphic designer consolidated it in a printer-friendly version.

Particular attention was devoted to the flyer text to make sure that it could be suitable for different kind of target stakeholders (public and private, patient associations, policy makers, scientific community, lay public etc.), remaining precise and concise.


The flyer was distributed to the project partners first and then externally with the invitation to the ADVANCE final event (D6.10) and it has been made available on the ADVANCE website (www.advance-vaccines-eu) and on the VAC4EU website (www.vac4eu.org) in a format easy to print in order to be used and distributed in any occasions.

A paper version of the flyer was distributed to the final event participants.

2.3 Webinars

The internal communication strategy has been enhanced with the organization of webinars intended to increase the understanding of the ADVANCE developments among the project participants. A number of internal webinars were held to present the tools resulting from the WP4 activities, with more than 75 attendees in total:

- Benefit-risk monitoring of vaccines: a dashboard, 07/03/2017, Tom De Smedt,
- CodeMapper - A web-application for the semi-automatic coding of case definitions. Theory & practice, 22/03/2017, Benedikt Becker
- Validation of case-finding algorithms in healthcare research: analytical interrelations between validity indices, 21/04/2017, Kaatje Bollaerts
- Bias due to disease - and exposure misclassification in studies of vaccine effectiveness: a simulation tool, 08/05/2017, Kaatje Bollaerts
- Component analyses, 05/06/2017, Rosa Gini
- Are the ADVANCE datasources valid? Feability assessment of databases: methods and results on coverage, events and populations, 17/11/2017, Miriam Sturkenboom
- Coverage POC 1, 22/11/2017, Hanne Dorthe
- ADVANCE WP5 POC Results Risk Pillar, 28/11/2017, Daniel Weibel
- ADVANCE-WP5-Proof-of-Concept: Results from Benefits Pillar, 07/12/2017, Myint Tin Tin Htar
- ADVANCE system testing: benefit-risk analysis of a marketed vaccine using cohort modelling and multi-criteria decision analysis, 11/12/2019, Kaatje Bollaerts

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2.4 The ADVANCE SharePoint

The ADVANCE Share Point site is a private shared workspace for partners and associate partners to upload and review documents related to the project. Share Point comprises a multipurpose set of Web technologies backed by a common technical infrastructure. Access to this service for the ADVANCE project has been provided by the partner Sciansano as they have a license for their organisation. Sciansano set up a SharePoint site to the ADVANCE project, a username and password has been provided to the key people from the partner and associated partner organisations only.


The Share Point area allows partners to work together to create documents or share information within a specific Work Package and access to documents can be set to “no access”, “read only” or “full editing” rights.

Share Point has been reorganised and updated to make this tool more user friendly with the key documents available for partners’ access. In addition, key project documents have been uploaded to Share Point to ensure its proper archiving. Share Point will be maintained by Sciansano for the period of five years after the end of the project.


2.5 Distribution lists

Several distributions lists have been created at the start of the project and during its implementation. These can be used by any participant depending on the discussion topic. Synapse is in charge of updating the lists with the information received from participants. The table below shows the distribution lists created during the project (almost 50):

ADVANCE Admin	admin@advance-vaccines.eu
ADVANCE All	all@advance-vaccines.eu
ADVANCE Associate	associate@advance-vaccines.eu
ADVANCE Bulletin	newsletter@advance-vaccines.eu
ADVANCE COC Consultation	coc_consultation@advance-vaccines.eu
ADVANCE Comm	comm@advance-vaccines.eu
ADVANCE CT	ct@advance-vaccines.eu
ADVANCE EFPIA	efpia@advance-vaccines.eu
ADVANCE Fingerprint	fingerprint@advance-vaccines.eu
ADVANCE INFO	info@advance-vaccines.eu
ADVANCE NON-EFPIA	non-efpia@advance-vaccines.eu
ADVANCE PI	pi@advance-vaccines.eu
ADVANCE POC CT	poc-ct@advance-vaccines.eu
ADVANCE POC DB	POC-DB@advance-vaccines.eu
ADVANCE POC PERTUSSIS	poc-pertussis@advance-vaccines.eu
ADVANCE POC Statisticians	poc-statisticians@advance-vaccines.eu
ADVANCE POC1.2 Study Team	POC1.2_study_team@advance-vaccines.eu
ADVANCE POCOUTLINE	advance-pocoutline@advance-vaccines.eu
ADVANCE Steering Committee	sc@advance-vaccines.eu
ADVANCE USER	advance-user@synapse-managers.com

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ADVANCE VAC4EU	vac4eu@advance-vaccines.eu
ADVANCE WP1	wp1@advance-vaccines.eu
ADVANCE WP1-CoC	wp1_coc@advance-vaccines.eu
ADVANCE WP1-Communication	wp1_communication@advance-vaccines.eu
ADVANCE WP1-Governance	wp1_governance@advance-vaccines.eu
ADVANCE WP1-Quality	wp1_quality@advance-vaccines.eu
ADVANCE WP2	wp2@advance-vaccines.eu
ADVANCE WP3	wp3@advance-vaccines.eu
ADVANCE WP3 SURVEY	wp3_survey@advance-vaccines.eu
ADVANCE WP4	wp4@advance-vaccines.eu
ADVANCE WP4 HET Confounding	wp4-het-confounding@advance-vaccines.eu
ADVANCE WP4 HET EXPO	wp4-het-expo@advance-vaccines.eu
ADVANCE WP4 HET Outcomes	wp4-het-outcomes@advance-vaccines.eu
ADVANCE WP4 HET POP	wp4-het-pop@advance-vaccines.eu
ADVANCE WP4dev_BoD	wp4dev_bod@advance-vaccines.eu
ADVANCE WP4dev_COD	wp4dev_cod@advance-vaccines.eu
ADVANCE WP4dev_COV	wp4dev_cov@advance-vaccines.eu
ADVANCE WP4dev_EFF	wp4dev_eff@advance-vaccines.eu
ADVANCE WP4dev_HET	wp4dev_het@advance-vaccines.eu
ADVANCE WP4dev_ONT	wp4dev_ont@advance-vaccines.eu
ADVANCE WP4dev_SEQ	wp4dev_seq@advance-vaccines.eu
ADVANCE WP5	wp5@advance-vaccines.eu
ADVANCE WP5 B/R ANALYSIS	wp5-br-analysis@advance-vaccines.eu
ADVANCE WP5 BENEFIT	wp5-benefit@advance-vaccines.eu
ADVANCE WP5 COVERAGE	wp5-coverage@advance-vaccines.eu
ADVANCE WP5 PREFERENCE SOLICITATION	wp5-preference-solicitation@advance-vaccines.eu
ADVANCE WP5 RISK	wp5-risk@advance-vaccines.eu
ADVANCE WP6	wp6@advance-vaccines.eu
ADVANCE WP7	wp7@advance-vaccines.eu

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2.6. Meetings and workshops


During the course of the project the following consortium meetings have been organised to ensure internal communication between project partners and work packages:

- 10 General Assembly Meetings have been held, including participation of Scientific Advisory Board in four occasions:

ADVANCE Kick-off Meeting	October 17 th & 18 th , 2013	Barcelona, Spain
2nd General Assembly Meeting	March 27 th & 28 th , 2014	Barcelona, Spain
3rd General Assembly Meeting	September 18 th & 19 th , 2014	Veyrier-du-Lac, France
4th General Assembly Meeting	April 20 th & 21 st , 2015	Barcelona, Spain
5th General Assembly Meeting	September 28 th & 29 th , 2015	Barcelona, Spain
6th Forum & General Assembly Meeting	April 20 th & 21 st , 2016	Madrid, Spain
7th General Assembly Meeting	October 4 th & 5 th , 2016	Barcelona, Spain
8th General Assembly Meeting	May 17 th & 18 th , 2017	Barcelona, Spain
9th General Assembly Meeting	October 10 th & 11 th , 2017	Barcelona, Spain
10th General Assembly Meeting	September 6 th & 7 th , 2018	London, UK

- 14 workshops related to different WP activities (including Governance and Communication workshops)

WP1 & WP3	November 2013	London UK
WP4	November 2013	Brussels, Belgium
WP1	March 2014	Barcelona, Spain
WP5	March 2014	Brussels, Belgium
WP3	June 2014	London, UK
WP4	September 2014	Brussels, Belgium
WP1	November 2014	London, UK
WP5	January 2015	Rotterdam, Netherlands
WP4	March 2015	Brussels, Belgium
WP3	November 2015	London, UK
WP1	December 2015	London, UK
WP4/WP5	June 2016	Leuven, Belgium
WP1	March 2017	London, UK
WP1	June 2017	London, UK


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- 14 face-to-face Steering Committee meetings including the ADVANCE **Bootcamp**

Annecy	April 2014
Rotterdam	July 2014
Brussels	August 2014
Amsterdam	November 2014
Rotterdam	January 2015
London	December 2015
Madrid	April 2016
Brussels	Mai 2016
Montserrat	September 2016
Brussels	February 2017
Leuven	January 2018
(Bootcamp)	
Barcelona	June 2018
London	September 2018
Brussels	March 2019

2.7. Teleconferences

A number of teleconferences have been held to communicate about the ongoing activities of the ADVANCE project. These include regular weekly Coordination Team teleconferences, monthly Steering Committee meetings, weekly WP5 POC teleconferences and other related to different work packages and task forces. Furthermore, weekly teleconferences have been organised during the last three months of the project to plan and communicate on the sustainability of the project.

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ANNEXES

Annex 1 Examples of ADVANCE Bulletins -



PDC-1 studies results were presented at the ADVANCE 8th GAM

At the 8th GAM, 7 databases covering a source population of 45 million persons presented their eligibility assessments which were used to verify their eligibility for participation in the PDC-1 pillars. Eligibility assessment sheets describe the structure of the database, population representativeness, vaccination capturing and event extractions and comparisons with external benchmarks. Eligibility assessment sheets are available in the PDC-1 report.

The coverage, benefit and risk pillar presented the results from the PDC-1 study. Coverage estimates were high in all countries and very consistent and comparable with external benchmarks. Pertussis incidence was quite comparable across databases and with surveillance data. Heterogeneity between databases was more pronounced in the risk pillar, especially for the outcomes that were symptoms, that may not be recorded in databases that capture only hospitalizations. This heterogeneity, based on the type of database needs to be considered carefully.

The benefit risk analysis were presented including the results on the preferences that were elicited the day before the GAM.

The Scientific Advisory Board complimented the study teams with the work done, and was happy to see so much real data.

The reports are currently undergoing the review by ADVANCE Consortium.




Two ADVANCE White papers were submitted to IMI

We are pleased to announce that these two White papers have been submitted to IMI:

WP3 D3.5 White paper "Procedures for data access, sharing, linkage and integration, including privacy and ethics". Read more [here](#).

WP4 D4.9 White paper "Methods for vaccine benefit-risk monitoring, including vaccine coverage, safety and effectiveness". Read more [here](#).

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WP1 Governance Workshop

The draft report of Governance workshop will be sent all participants beginning of July for comments. The final report will be made then publicly available on the ADVANCE website by end of July.

The outline of the WP1 Write paper has been accepted by the ADVANCE CT. It aims mainly to address public-private interactions challenges and provide governance materials and recommendations; the CoC which has been already published will be referenced as well. It will be submitted to IMI and ECDC by the end of September.

WP1 Communication Workshop


The London School of Hygiene & Tropical Medicine (LSHTM) organised on 29 June 2017 an ADVANCE workshop on communication of risk-benefits of vaccines. The objective of the workshop was to agree on the format and content of a practical guidance document (to be submitted as Deliverable 1.12) with step-by-step recommendations addressing various scenarios where communication is critical. The workshop also aimed to identify challenges and specificities of benefit-risk monitoring studies to be included in a communication plan (using the POCs as an example), agree on how to communicate results about benefit-risks of vaccination coming from public-private partnerships and identify case studies that can be used to illustrate the guidance document. The denomination "public-private collaboration" was deemed more acceptable to the public than "public-private partnership" and will therefore be used in the guidance.

The title of the deliverable will be revised as: "Developing communication strategies on vaccine benefit and risk: Guidance for public-private collaborations" in order to highlight that, although anyone will be able to use the guidance, it will be developed specifically for members of public-private collaborations (PPCs) working on benefits and risks of vaccination. A distinction was made between three interest groups: the users, i.e. the institutions who will use the guidance document to develop their own communication strategy on benefits and risks of vaccination, including regulators, public health institutes, patient organisations, manufacturers or academic research organisations; the audience (e.g. the general public) targeted by the users through various channels and using various messages; and the stakeholders, which comprise any organisation or institute with interest in the benefits and risks of vaccinations and need to be involved in the development of the communication strategy.

The complex role of healthcare professionals was discussed extensively as it was acknowledged that they also require help on how to communicate with patients and how to listen to them. As some healthcare professionals are themselves hesitant about vaccination, it is important to give them clear and balanced information and they should be included both as audience and stakeholder of the communication strategy, as well as representing a possible channel of communication with the public.

It was agreed that a component of public trust is a good understanding of how the information on benefits and risks of vaccines was obtained. The communication should be transparent about the complexity of the methods, the observational nature of the data, the statistical uncertainty as well as the role and usefulness of a PPC.

The group worked on the table of content for Deliverable 1.12 and assigned partners for the different sections of the document. Timelines were agreed to submit the Deliverable by 29th of September 2017.

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ADVANCE Code of Conduct

ADVANCE project publishes Code of Conduct to improve future vaccine studies. The [ADVANCE Code of Conduct](#), now available in the journal *Vaccine* and featured in the IMI JU newsletter (67th Edition), was developed by members of a wide range of different organisations including regulatory and public health authorities, vaccine manufacturers and academic organisations.

Its development was guided by three core and common values (best science, strengthening public health, transparency), and a review of existing guidance and relevant published articles.

The document includes 45 recommendations in 10 topics: scientific integrity, scientific independence, transparency, conflicts of interest, study protocol, study report, publication, subject privacy, sharing of study data, and research contract. In the publication, the authors said they hope that 'adoption of the ADVANCE Code of Conduct by all partners involved in a study will facilitate and speed-up its initiation, design, conduct and reporting.

The Code of Conduct is one of the four components of good practice guidance for vaccine studies, which will also include recommendations for good governance, quality management and communication on vaccine safety. This important deliverable of the ADVANCE project aims to pave the way for a European framework capable of rapidly delivering reliable data on the benefits and risks of marketed vaccines.


ADVANCE recent publications

Articles

1. Benedikt F.H. Becker, Paul Aritlach, Silvana Romio, Erik M. van Meijigen, Daniel Weibel, Miriam C.J.M. Sturkenboom, Jan A. Kars, for the ADVANCE consortium (2017) *CodeMapper: semiautomatic coding of case definitions. A contribution from the ADVANCE project. Pharmacoepidemiol Drug Saf.* 2017;1-8. 2. Read more [here](#).
2. Priya Bahl, Julianna Fogd, Daniel Morales, Xavier Kurz, on behalf of the ADVANCE consortium. Application of real-time global media monitoring and 'derived questions' for enhancing communication by regulatory bodies: the case of human papillomavirus vaccines. *BMC Medicine*; 15(1):91. Read more [here](#).
3. Xavier Kurz, Vincent Sauchau, Patrick Mahy, Stefan Gitzmann, Lieke Maria van der Aa (2017) *The ADVANCE Code of Conduct for Collaborative Vaccine Studies. Vaccine*; 4;35(15):1844-1855. Read more [here](#).

Upcoming ISPE 2017 posters and presentations

1. Scott McDonald, Danielle Nijsten, Kaatje Bollaerts, Jorgen Bauwens, Tom de Smedt, Miriam Sturkenboom, Susan Hahne (2017) *Methodology to estimate the health burden of adverse events following immunization: a contribution from the ADVANCE project. ISPE 2017 (Poster).*
2. Miriam Sturkenboom, Caitlin Dodd, Ana Correia, Hanne Dorthe-Emborg, Taita Duarte-Salles, Elisa Martin, Consuelo Huerta, Silvia Lucchi, Gino Piccoli, Lara Tramentan, Lieke van der Aa, Daniel Weibel, Benedikt Becker, Giuseppe Roberto, Marius George, Rosa Gini (2017) *Methodology to assess eligibility of electronic healthcare databases to conduct vaccine coverage, risk and benefits studies in Europe- contribution of the ADVANCE project. ISPE 2017 (Poster).*

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3. Rosa Gini, Caitlin Dodd, Kaatje Bollaerts, Claudia Bartolini, Giuseppe Roberto, Consuelo Haerta, Elisa Martin, Talita Duarte Sales, Gino Piccoli, Lara Tramontan, Benedikt Becker, Charlotte Switzer, Sonja Banga, Jorgen Baizews, Daniel Weibel, Miriam Starckenboom (2017) Algorithms to identify pertussis in four European primary care databases - the ADVANCE project. ISPE 2017 (Oral presentation).

4. Kaatje Bollaerts, Alexandros Reikvas, Tom De Smedt, Caitlin Dodd, Nick Andrews, Rosa Gini (2017) Analytical interrelations between validity indices for validation of case-finding algorithms in healthcare data research: a contribution from ADVANCE. ISPE 2017 (Oral presentation).

Potential congresses for ADVANCE dissemination

A list of congresses and events where it is advisable to present the results of ADVANCE is available on [Shorpoint](#). To ensure that the ADVANCE results are adequately disseminated and that all the stakeholders are reached, all the project participants are invited to inform as soon as possible their work-package leaders about their willingness to participate in any of these events. The procedure for the internal approval for short communication is described in the deliverable 6.2, [Project Handbook](#).

ADVANCE WP4 webinars summary (March-June 2017)

Title: Benefit-risk monitoring of vaccines: a dashboard

Date: 07/03/2017

Speaker: Tom De Smedt

Title: CodeMapper - A web-application for the semi-automatic coding of case definitions. Theory & practice

Date: 22/03/2017

Speaker: Benedikt Becker

Title: Validation of case-finding algorithms in healthcare research: analytical interrelations between validity indices

Date: 21/04/2017

Speaker: Kaatje Bollaerts

Title: Bias due to disease - and exposure misclassification in studies of vaccine effectiveness: a simulation tool

Date: 05/05/2017


Speaker: Kaatje Bollaerts

Title: Heterogeneity in disease misclassification: the component strategy

Date: 20/06/2017

Speaker: Rosa Gini

All the webinar sessions have been recorded and are available on [Shorpoint](#).

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The 9th ADVANCE Forum/General Assembly Meeting

We are pleased to announce that the 9th ADVANCE Forum/General Assembly Meeting will be held on the 10th and 11th of October 2017 in Barcelona.





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[Advancing medicines](#)

The research leading to these results has received support from the Innovative Medicines Initiative Joint Undertaking under ADVANCE Consortium Agreement n° 115557, resources of which are composed of financial contribution from the European Union's Seventh Framework Programme (FP7/2007/2013) and EFPIA, and private industrial contributions.

For mailing information, see: info@advancingmedicines.eu

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ADVANCE Bulletin Issue 2018

Dear partners, dear friends,

Last Tuesday 21st of May 2018 the ADVANCE project was reviewed by an international panel of experts in the framework of the IMI Million Health. The panel was composed of internationally recognized experts: [Prof. Maria Sanchez De Los Rios](#), Chair of the IMI Scientific Committee; [Dr. Robert J. Colquhoun](#), Assistant Professor of Epidemiology at the Colorado School of Public Health; [Prof. A. Elizabeth Hillier](#), Consultant Epidemiologist at Public Health England; and [Dr. Nancy Birkbeck](#), Consultant in Pharmacogenetics.

The consortium, represented by the Steering Committee, presented the main achievements of ADVANCE in its first 30 months. It was also a great opportunity to exchange with the reviewers on the project hurdles and future challenges (suitable methods, POC studies, impact, overall impact, sustainability beyond the project, etc.).

The discussion was lively during the whole day, with plenty of questions that showed the genuine interest and contribution spirit from the reviewers. All ADVANCE stakeholders stood up on a hour and participated in the discussion providing insights and clarifications where needed.

Although the full report of the review will be received from IMI by the end of June, we have already received a first feedback from the reviewers, which is globally encouraging.

Outlines

- Congratulations, regardless that sample project;
- The presentations helped to clarify a good overview of the work accomplished and how it is integrated, of setting out the mission and vision and motivating people;
- Several recognized that personally is challenging but pleased to see that project has achieved a good engagement of different stakeholders;
- Important results have been presented today that were significantly more advanced than what was in the overall partner's report;
- Methodological work much appreciated, will be valuable suitable ADVANCE also for public health stakeholders;
- Reviewers appreciated that some work was done on governance models as part of thinking of post-ADVANCE (last no. 1,2,3,4), but see also negative notes;
- Reviewers encourage you to provide in future reports a more comprehensive view on how the different components of the project are advancing and interacting.

Outlines

- The general national seems uncertain about the terminology, signs and/or icons versus marketing;
- Several comments underlined whether the proposed governance models for the future post-ADVANCE (and also in regards internal) will actually be tested during the course of ADVANCE with the POC studies, could be places of governance model (certain example, CoC, ...); (some answers were provided in the final feedback session);
- There was a major concern about the limitations of the data bases and usefulness of databases you currently have access to, mismatch between expectations raised by your CEO and what you will actually be able to achieve; mismatch between IT solutions and methodology development with what will be achievable in real world given the databases available;
- Was/were an appropriate work package; not convinced that effort has justified the end product.

Recommendations


- Reviewer what you will be able to achieve, manage expectations;
- Do a better job at communication with external stakeholders to gain more input on governance models, in particular, national public health institutes, perhaps via a workshop;
- Governance models suggestion that you could look for models suitable health system, e.g. diabetes;
- Recommendations not to publish results without appropriate due diligence.

We hope that you will find this feedback inspiring and we would like to thank you all, partners and associate partners, for your efforts and contributions to the project. Without your work and support we wouldn't have made it to this stage. The project is now halfway and still a lot of work has to be done and many milestones have to be achieved within the remaining 30 months. Keep on board!

You'll find all the slides here: [IMI Bulletin Review](#)







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Annex 2 - ADVANCE flyer

Front and back

 <p>Accelerated Development of VAaccine beNefit-risk Collaboration in Europe</p>  <p>imi innovative medicines initiative</p>	<p>Unique capacity in Europe for high quality and rapid studies/monitoring activities on vaccine benefits and risks</p>
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Interior pages



ADVANCE

Accelerated Development
of Vaccine Benefit-risk Collaboration in Europe

What is ADVANCE?

ADVANCE is a project that was supported through the Innovative Medicines Initiative (IMI) in 2013. It has brought together scientists from all major stakeholders interested in post-licensure monitoring of the coverage, benefits and risks of vaccines. The ADVANCE consortium established a public-private collaboration (PPC) to enable rapid and comprehensive development of post-marketing vaccine evidence generation which was not possible in Europe before the project was initiated. Regulators such as the European Medicines Agency (EMA), public health institutes including the European Centre for Disease Control & Prevention (ECDC), numerous vaccine manufacturers and many of Europe's leading academic institutions collaborated to create best practice guidance, methods, tools and capacity to generate rapid evidence on vaccines from existing healthcare data. The ADVANCE consortium has demonstrated that the enormous resource of existing and fragmented European real-world healthcare data can be used to generate actionable evidence on vaccine coverage, benefits and risks for drug regulatory agencies, public health agencies, vaccine manufacturers, health care professionals, and patients.

How did we ADVANCE?

During the project's lifetime, the ADVANCE consortium developed and tested procedures, methods, and workflows to ensure readiness for rapid generation of evidence on coverage, benefits, and risks of vaccines. ADVANCE's deliverables and tools are publicly available at www.advance-vaccines.eu.

Achievements include:

Environment & governance readiness

- Engagement of 47 partners across 19 European countries: 16 academic/public research institutions; 10 public health organisations; 9 national drug regulatory agencies, including the EMA and ECDC; and 7 vaccine manufacturers; 3 small medium enterprises (SMEs); 2 charities.
- Development of best practices (code of conduct) and governance for collaborative vaccine studies.

Data source readiness


- A simple common data model for multi-database studies.
- Detailed processes and workflows to assess whether data sources are fit for purpose.
 - Data characterisation of 19 data sources in 8 countries.
 - Age, calendar-year, and gender-specific incidence rates for 25 events of interest.
 - Vaccine coverage estimates by birth cohort, calendar-year, age and target groups.
- Interactive Dashboard to show near real time monitoring of vaccine coverage, benefits and risks.

Methods readiness

- Overview of existing and novel methods for estimation of vaccine coverage, benefits and risks estimation
- Online tools supporting generation of evidence:
 - CCodemapper: maps outcome definitions into diagnostic codes across a range of vocabularies.
 - VaccO: a vaccine ontology.
 - Interrelation tool: estimation of outcome validity measures.
 - Vaccine effectiveness misclassification tool.
 - Benefit-risk monitoring dashboard for visualising vaccine coverage, benefits/risks.

Study readiness

- Best practice guidance implemented and tested in multi-database studies.
- Templates for study outlines, protocols, declarations of interest, statistical analysis plans, and reports.
- Publicly available protocols and results.
- Double-coded SAS and R syntax/programs to transform raw healthcare data into required evidence.
- Operational platforms for the transfer, sharing, and pooling of data.

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Implementation plan

- Blueprint describing how to use the ADVANCE systems for monitoring vaccine coverage, benefits and risks in Europe, created by the ECDC, that has undergone public consultation.



The ADVANCE project funding by IMI ends in March 2019. To implement its vision and enable actionable and rapid evidence-generation on the effects of vaccines in a collaborative manner, the consortium has decided to create a multi-stakeholder scientific community and an operational study network, which will have an official status as a legal entity with articles of incorporation with the following principles:

- VAC4EU will be a not-for-profit legal entity (international association), with both personal (community) and institutional membership (study network)
- VAC4EU will provide access to a well characterized public study network, which can provide data access and perform studies for different external requesters (e.g. vaccine manufacturers, European Commission, regulators, public health institutes) or internally
- VAC4EU will have independent scientific and audit committees for oversight.

Acknowledgement

- The research leading to these results has received support from the Innovative Medicines Initiative Joint Undertaking under ADVANCE grant agreement n° 115557.




ADVANCE Partners

- Aarhus Universitetshospital (Denmark)
- Agencia Española de Medicamentos y Productos Sanitarios (Spain)
- Agenzia Regionale di Sanità, Toscana (Italy)
- Azienda Sanitaria Locale della Provincia di Cremona (Italy)
- Erasmus Universitair Medisch Centrum Rotterdam (Netherlands)
- European Centre for Disease Prevention and Control (Sweden)
- European Medicines Agency (United Kingdom)
- GlaxoSmithKline Biologicals, S.A. (Belgium)
- Janssen Vaccines - Prevention BV, (Belgium)
- Jordi Gol Fundació Institut Universitari per a la Recerca a l'Atenció Primària de Salut Jordi Gol i Gurina, Barcelona (Spain)
- Karolinska Institutet (Sweden)
- London School of Hygiene and Tropical Medicine (United Kingdom)
- Medicines and Healthcare products Regulatory Agency (United Kingdom)
- Merck Sharp & Dohme Corp (USA)
- National Institute for Public Health and the Environment (Netherlands)
- Novartis Pharma AG (Switzerland)
- P95 (Belgium)
- Pfizer Limited (United Kingdom)
- Royal College of General Practitioners (United Kingdom)
- Sanofi Pasteur (France)
- Sciensano (Belgium)
- Società Servizi Telematici SRL (Italy)
- Statens Serum Institut (Denmark)
- Synapse Research Management Partners, S.L. (Spain)
- Takeda Pharmaceuticals International AG (Switzerland)
- Tampereen Yliopisto (Finland)
- The Open University (United Kingdom)
- The University of Surrey (United Kingdom)
- Universitat Basel (Switzerland)

ADVANCE Associate partners

- Brighton Collaboration Foundation (Switzerland)
- Foundation for the Promotion of Health and Biomedical Research (Spain)
- French National Agency for Medicines and Health Products Safety (France)
- Hellenic Medicines Agency, National Organisation for Medicines (Greece)
- Hellenic Centre for Disease Control and Prevention (Greece)
- Hellenic National School of Public Health (Greece)
- Imperial College London (UK)
- Institut de Recherche et Développement (France)
- Irish Medicines Board (Ireland)
- Italian Medicines Agency (Italy)
- National Center for Epidemiology (Hungary)
- National Institute for Health and Welfare (Finland)
- Polish Medicines Agency (Poland)
- Public Health England (UK)
- State Medicines Control Agency (Lithuania)
- University Medical Center Utrecht (Netherlands)
- University of Athens (Greece)
- University of Messina (Italy)
- VACCINEGRID foundation (Switzerland)