

D5.7 Report on synergies identified and collaborations developed with other initiatives

DRIVE

**Development of Robust and
Innovative Vaccines Effectiveness**

[WP5 – Communications]

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¹ Use one of the following codes:

R: Document, report (excluding the periodic and final reports)

DEM: Demonstrator, pilot, prototype, plan designs

DEC: Websites, patents filing, press & media actions, videos, etc.

OTHER: Software, technical diagram, etc.

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Abbreviations

DRIVE: Development of Robust and Innovative Vaccine Effectiveness

ECDC: European Centre for Disease Prevention and Control

EFPIA: European Federation of Pharmaceutical Industries and Associations

EMA: European Medicines Agency

IVE: Influenza Vaccine Effectiveness

QCAC: Quality Control & Audit Committee

Executive Summary

Identifying synergies and collaborations established with other initiatives

AIMS

The aim of deliverable 5.7 is to report synergies explored by DRIVE with external initiatives during the first reporting period of the project (2017-2018). The deliverable also presents a strategy for extending synergy identification process to support ongoing research activities.

METHODS

To identify relevant initiatives, we conducted a survey among DRIVE Work Package leaders. All WP leaders were asked to complete a survey regarding the relevance of the identified initiatives to their WPs as well as the feasibility of collaboration. We propose a process to identify and establish further synergies based on a method used previously by another IMI project.

RESULTS

The deliverable reports information about synergy explored with 6 external initiatives from various information sources within the project. In addition, the deliverable also reports interactions (ongoing/planned) with statutory and non-statutory stakeholders for influenza effectiveness studies conducted by the project.

CONCLUSIONS

DRIVE has made initial steps to create synergies by directly engaging with key stakeholders and previous projects. These initial efforts will be complemented by a systematic approach to identify synergies during the next reporting period.

DRIVE partners involved in T5.7

SURREY

Chapter 1: Introduction

The Development of Robust and Innovative Vaccine Effectiveness (DRIVE) project (funded by the Innovative Medicines Initiative) was established to explore brand-specific influenza vaccine effectiveness (IVE) in Europe. During the initial stage the project has formed links with national registries, hospital networks and primary care networks in Europe to collect data for a pooled analysis of IVE. The project has been set up as a public-private partnership involving a range of stakeholders for IVE studies including public health institutes, universities, small and medium-sized enterprises, vaccine manufacturers, and a patient organization.

The focus of stakeholder interactions during the first reporting period has been in relation to informing public health institutions (PHIs) of DRIVE and establishing sustainable partnerships with them. Interactions with the relevant stakeholders during the reporting period was also assessed.

Project structure

The DRIVE project structure is formed of eight scientific work packages supported by a steering committee, independent scientific committee and a quality control and audit committee.¹ Work Packages 1–5 and 8 are coordinated by WP6. A series of IVE studies and a pooled analysis are conducted by WP7 under the supervision of the Independent Scientific Committee. The WP8 and the Quality Control & Audit Committee have specific focus in the project in ethical requirements and quality/compliance of the studies, respectively.

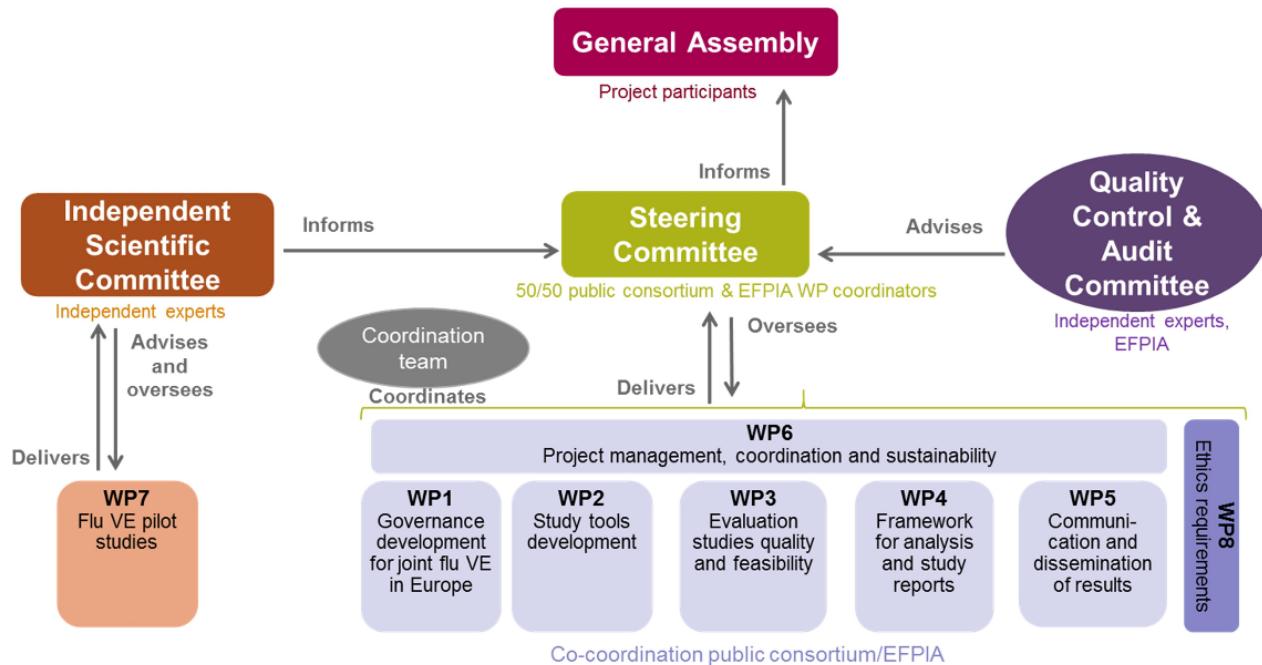


Figure 1: Project structure of DRIVE¹

Chapter 2 - Methods

The aim of the contributing task for this deliverable (T5.7) was to optimise the use of the DRIVE consortium resources by establishing synergies with existing initiatives that were able to provide experiences and best practices in the field of IVE which could assist in achieving the goals of the DRIVE project.

Identification of synergies – Stage 1

During the initial reporting period, the consortium partners actively pursued synergies identified during the proposal stage of the project and those within the professional networks of the partners. The outcome/status of these synergies were reported in the annual project report. To complement this project level activity, we conducted a survey among the DRIVE work package leads/co-leads to understand work package level activity to reach out to external initiatives. The results from these two activities are reported in this deliverable.

The survey sent to the work package leads captured the following information in their corresponding work streams.

- Project title
- Website
- Synergy areas identified
- If any initial discussion were conducted external initiatives
- Status of any collaborations established with DRIVE
- Barriers to collaboration
- Planned synergies with DRIVE

Identification of synergies – Stage 2

In order to explore further synergies, WP5 has planned to subsequently conduct a systematic approach for identifying and establishing further synergies that could potentially enrich the ongoing IVE studies and other methodological research carried out in DRIVE. The method for this process has been adapted from the method used by the IMI ADVANCE project to identify and establish synergies.² The adapted method is indicated as a part 2 of the 2-stage synergy identification process planned by DRIVE WP5 in Figure 1.

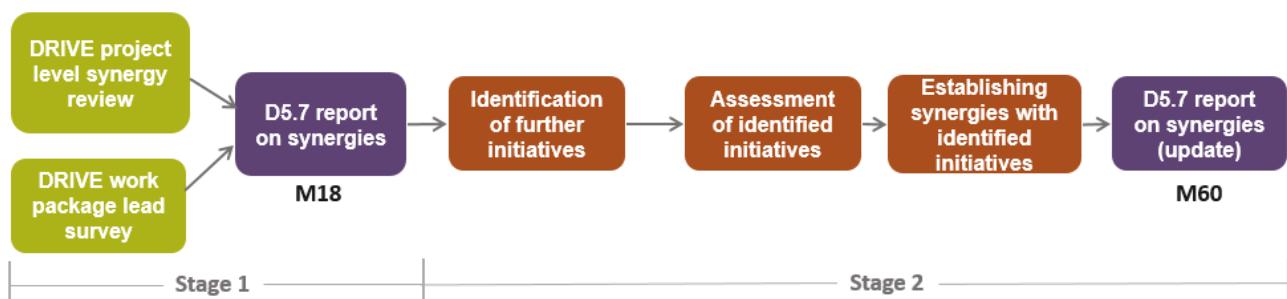


Figure 2: Synergy identification process in DRIVE

The process planned for stage 2 is outlined below.

1. Identification of further initiatives

We will search for related external initiatives in funding databases and project registries (e.g. Community Research and Development Information Service (CORDIS),³ Consumers, Health and Food Executive Agency (CHAFEA),⁴ IMI project inventory⁵). We will analyse the results and extract key information that will be useful for assess the relevance for DRIVE.

2. Assessment of identified initiatives

We will identify mapping terms for each the work packages based on the scope and nature of the work package activities. We will use these mapping terms to assess the tabulated search results and identify relevancy of the identified external initiatives to each work package. The mapped initiatives will be used to formulate synergy maps that will help to understand which initiatives are most useful for DRIVE to establish synergies during the period of the project.

3. Establishing synergies with identified initiatives

Based on the assessment results the work packages will select and prioritise the initiatives that could form beneficial synergies for their ongoing and future work. The coordination team will then advice on a utilisation strategy to streamline potential synergies and insert across the various work streams in the project.

Chapter 3 - Results

Proposed list of synergies at the inception of DRIVE

At the inception of the DRIVE project, the consortium considered to continue scientific outputs produce by a number of related European initiatives that had achieved methodological advancements in the vaccine research. These identified initiatives and their relevance were signposted in the project proposal (Table 1).

Table 1: Proposed list of synergies in the DRIVE proposal

Project Title	Relevance
Accelerated development of vaccine benefit-risk collaboration in Europe (ADVANCE)	Governance model, identify data sources, data access and linkage, study site selection, data collection, pilot study processes, EU databases mapping and quality management.
Influenza Monitoring Vaccine Effectiveness (I-MOVE/+)	Protocols, standard operating procedures, audits
Vaccine European New Integrated Collaboration Effort (VENICE).	Surveys on influenza vaccination programmes in EU member states and national contact points
Global Influenza Surveillance and Response System (GISRS)	Influenza virological surveillance for the annual strain selection that can be potentially enriched by DRIVE data
Global Influenza Initiative (GII)	Marketing authorisation holder (MAH) sponsored forum on seasonal influenza prevention exploring worldwide through vaccination, education, and international cooperation, as informed by virologic, epidemiologic, public health, and health economic data.
Global Influenza Hospital Surveillance Network (GIHSN)	Global public-private partnership network of public institutes applying a common core protocol to estimate influenza burden of disease and influenza vaccine effectiveness in hospital setting.
Europe-wide network to monitor the activity of influenza-like illness using volunteers via a web platform (INFLUENZANET)	Development of novel approaches to estimate vaccine effectiveness using participatory epidemiology

Results of the work package lead's survey about synergies with external initiatives

We received responses about 4 ongoing synergies for the work package lead's survey. The details of the initiatives and the status of the synergy is given below.

External initiative 1: Vaccine European New Integrated Collaboration Effort (VENICE)^{6,7}

Website: <http://venice.cineca.org/>

Funder: VENICE I (EC-DG SANCO), VENICE II (ECDC)

The VENICE report on *Seasonal influenza vaccination in Europe. Vaccination recommendations and coverage rates in the EU Member States for eight influenza seasons: 2007–2008 to 2014–2015* has proven an important reference for several DRIVE activities.⁸ VENICE also shared the raw data behind a number of the graphs from one of their recent publications for the purposes of D3.1 and D3.3.

Current status of synergy: A request of information related to immunization information systems has been circulated within the Venice network, after contacting the project coordinator for clearance.

Barriers to collaboration: Barriers are to be verified after understanding more details about the possible synergy with DRIVE.

External initiative 2: International Federation of Pharmaceutical Manufacturers & Associations (IFPMA)⁹

Website: <https://www.ifpma.org/>

We have identified the potential of building on prior experience of IFPMA with sharing of market data between MAHs in relation to Competitions laws. This will be useful to understand the options we have in DRIVE to share market data among the MAHs within the boundaries of the competition laws. Potential for building synergies with the vaccine effectiveness task force are also being evaluated.

Current status of synergy: A presentation was given to the IFMPA - Influenza Vaccine Manufacturer's group on the genesis of DRIVE, the approach and limitations to identify brand availability. The IFPMA shared their current approach and experience with sharing of market data between the IFPMA, which has thusfar only been at the non-brand specific and country level in an anonymized fashion.

Barriers to collaboration: The IFPMA can currently only participate in an advisory role.

External initiative 3: Accelerated development of vaccine benefit-risk collaboration in Europe (ADVANCE)

Website: <http://www.advance-vaccines.eu>

Funder: Innovative Medicines Initiative

Current status of synergy:

No formal collaboration has taken place. In WP1, The ADVANCE Code of Conduct has been used as a pivotal reference in WP1 work on scientific independence, integrity and transparency.¹⁰ The ADVANCE Governance guidance was used to develop the starting governance model of the brand specific influenza vaccine effectiveness platform considering DRIVE specificities and constraints. DRIVE could be considered as a real life testing of ADVANCE governance guidance. The ADVANCE Governance guidance

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was presented at ESCAIDE with details about how the guidance will be used in DRIVE. The ADVANCE steering committee has been informed about this development.

In WP2, the ADVANCE web catalogue of data sources was explored to identify the existing electronic database relevant to collect vaccine related information or build VE studies for influenza.

In WP3, ADVANCE has been also informed that the quality criteria would be used as the starting point for assessing quality management of the VE studies in DRIVE.

In WP5, the methodology for identifying and establishing synergies with external initiatives reported in this deliverable has also been developed by adapting the corresponding process in ADVANCE.

Barriers to collaboration: The ADVANCE consortium will complete work in Q1 2019 and discussion with potential follow-up initiatives would need to be considered after this period.

External initiative 4: Influenza Monitoring Vaccine Effectiveness (I-MOVE/+)

Website: <https://sites.google.com/site/epiflu/Home>

Funder: ECDC/participating countries/WHO-EURO

I-MOVE(+) is a European multi-country collaboration network with 11 years of experience in influenza vaccine effectiveness studies. While the mandates of DRIVE and I-MOVE(+) are not identical (DRIVE focuses on brand-specific IVE and public-private collaboration/governance), there is a large potential for synergy between the two.

Current status of synergy:

Some DRIVE partners/collaborators have also participated in I-MOVE(+). The coordinators of I-MOVE(+) have been informed of DRIVE's results and invited to DRIVE meetings. The WP1 research agenda was sent to I-MOVE for comments. The development of DRIVE generic protocols has been informed by the ECDC/I-MOVE(+) protocols. A common workshop on study methodology was proposed.

Barriers to collaboration: Currently, the acceptability of the public-private partnership governance varies between European countries. If perceived conflicts of interest remain, they could be considered a potential barrier.

External initiative 5: European Scientific Working group on Influenza (ESWI)

Website: <http://eswi.org>

Current status of synergy: DRIVE was invited to participate in the ESWI meeting held in September 2018. DRIVE will contribute to the 20th anniversary of the ESWI due to be held in 2020.

Overall assessment of synergies with stakeholders during the 1st reporting period of DRIVE

The coordination team conducted assessment of overall interactions of DRIVE for the annual project report. In addition to the synergies that were reported in the previous section, the following projects were also approached for establishing synergies.

External initiative 6: Europe-wide network to monitor the activity of influenza-like illness using volunteers via a web platform (INFLUENZANET)¹¹

Website: <https://www.influenzanet.eu/>

Current status of synergy:

A series of teleconferences were held with some Influenzanet member organizations (Spain, Italy, The Netherlands). Subsequently, Influenzanet submitted a proposal for the DRIVE call for tenders.

The following initiatives have been considered as potential synergies by DRIVE although no synergy has not taken place yet.

- FLUCOP: Standardisation and development of assays for assessment of influenza vaccine correlates of protection (FLUCOP). Relevant stakeholders from FLUCOP have been contacted to gain from their expertise in laboratory assays and tools to help with the development of DRIVE deliverables.
- Global Influenza Hospital Surveillance Network (GIHSN) Some GIHSN member countries were invited to join the Annual Forum and to participate as Associate Partners. Definite collaboration agreements have not yet been finalized.
- Global Influenza Surveillance and Response System (GISRS), Global Influenza Initiative (GII): No formal collaboration has taken place with these initiatives yet.

Table 2 and Table 3 indicate interactions between DRIVE and various stakeholders as reported in the 1st annual report of DRIVE.

Table 2: DRIVE interactions with statutory stakeholders

Stakeholder	Profile	Type	Interactions occurred
European Centre for Disease Prevention and Control (ECDC)	Collection and dissemination of data on infectious diseases, provides scientific guidelines to perform epidemiological studies	Public	ECDC representative attended the DRIVE Annual Forum in September 2018 and presented a key note speech.
European Medicines Agency (EMA)	Initial and continuous benefit/risk assessment through scientific evaluation and safety monitoring of the vaccines developed by pharmaceutical companies	Public	EMA will be updated on the progress of the project after the results come out. Representative from EMA participated in the Annual Forum of DRIVE in Sept 2018. The relationship between DRIVE and EMA is maintained via 2 distinct channels: one lead by IABS-EU (overall communications about the project) and one through EFPIA/Vaccines Europe (regulatory procedure- /manufacturer obligations- oriented discussions).
National Public Health Institutes (NPHIs)	Implementation, management and monitoring of immunisation programmes. Communication with health professionals, observational	Public	Several European NPHIs have been approached in the context of participating as Associate Partners / through the DRIVE call for tenders. Discussions are underway to involve some of them as DRIVE Associate

Stakeholder	Profile	Type	Interactions occurred
	studies and monitoring of vaccines uptake.		<p>Partners.</p> <p>Experts from PHIs of Denmark, Finland, Ireland, Italy, the Netherlands, Norway, Slovenia and Valencia/Spain were interviewed on influenza vaccine procurement and distributions systems in their respective countries (D3.1) and provided historical data on influenza vaccine availability (D3.3). For D3.4, experts from Italy, Finland, Valencia and Austria were interviewed regarding the ethical committee evaluation process.</p>
National Regulatory Agencies (NRAs)	Initial and continuous benefit/risk assessment through scientific evaluation and safety monitoring of the vaccines developed by pharmaceutical companies	Public	During the pilot season, the focus has been on NPHIs. The European Medicines Agency proposed to liaise with the NRAs and inform them about the progress and challenges related to DRIVE.
Manufacturing Authorization Holder (MAH)	Implementation and funding of effectiveness studies in order to fulfil licensure requirements (risk management plan).	Private	Four MAHs are represented in DRIVE as partners and have participated actively in all WPs save for WP7.
World Health Organization (WHO)	Directing and coordinating authority on international health within the United Nations' system.	Public	An expert from WHO-Europe region was invited to join the DRIVE Independent Scientific Committee.
Universities and Research institutions	Education and Research on new vaccines for influenza disease	Public Private	Three universities participate in DRIVE as partners; a fourth (Medical University of Vienna / NIC Austria) joined as an Associate Partner during the pilot season.
European Federation of Pharmaceutical Industries and Associations (EFPIA) / Vaccine Europe	Group of Vaccine manufacturers.	Private	<p>DRIVE was presented at a meeting of the Influenza Vaccine Supply (IVS) International Task Force of the International Federation of Pharmaceutical Manufacturers & Associations (IFPMA).</p> <p>The MAH have also consulted IFPMA on the possibility to share market data between MAH for the purpose of implementing IVE research.</p>

Table 3: DRIVE interactions with non-statutory stakeholders

Stakeholder	Profile	Type	Interactions occurred
Healthcare Professionals (General Practitioners, Physicians, nurses, social workers, pharmacists etc)	Patient care, execution of the vaccination programs and vaccine administration. These professionals may also act as participations in vaccine studies or contribute to routine public health surveillance activities.	Public Private	No healthcare practitioners were directly contacted during the pilot season but are intended to be reach out via the Layer 2 communication plan in 2019
Health insurance company/systems	Reimbursement of influenza vaccines, interest in reducing health care resources used due to influenza disease.	Public Private	No insurance systems were contacted during the pilot season.
Patient organizations	May represent (specific groups) of vaccine recipients. Communication to their stakeholders on the benefit and risk of vaccines.	Public	One patient organization (COMO) participates in DRIVE as a partner. Others are intended to be reach out via the Layer 2 communication plan in 2019.

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