5.5 Report on the collected feedback from Layer 1 Stakeholders

777363 – DRIVE

Development of Robust and Innovative Vaccine Effectiveness

WP5 – Communications

Lead contributor	Sharon McHale (14 –Seqirus)
	Miriam Levi (4 – UNIFI)
Other contributors	Riia Järvenpää (6 – THL)
	Laurence Torcel-Pagnon (12 - Sanofi Pasteur)
	Samantha Nye – (COMO)
	Topi Turunen (1 – FISABIO)
	Hanna Nohynek (6 – THL)

Due date	
Delivery date	31 December 2018
Deliverable type	R
Dissemination level	PU

Description of Work	**Version**	**Date**
	V0.1	25 OCT 2018

Document History

Version	Date	Description
V0.1	25 OCT 2018	First Draft
V0.2	04 NOV 2018	Second draft
V0.3	06 DEC 2018	Third Draft
V0.4	15 Dec 2018	Fourth Draft
V0.5	31 Dec 2018	Final Version

Table of contents

Abbreviations

DRIVE	Development of Robust and Innovative Vaccine Effectiveness
ECDC	European Centre for Disease Prevention and Control
EMA	European Medicines Agency
EU	European Union
PHI	Public Health Institute
VE	Influenza Vaccine Effectiveness
VWP	Vaccines Working Party
WP	Work Package

Publishable Summary

DRIVE has undertaken a number of activities to capture feedback from Layer 1 stakeholders, which include the European Medicines Agency (EMA), European Centre for Disease Prevention and Control (ECDC), World Health Organization (WHO), Strategic Advisory Group of Experts (SAGE), Public Health Regulatory Bodies, Directorate-General (DG) Sante, National Immunisation Technical Advisory Groups and National Public Health Institutes:

- a web-based communications survey (as described in deliverable 5.3)
- the 2018 DRIVE Annual Forum (as described in deliverable 5.6)
- a communications workshop at the 2018 DRIVE Annual Forum (as described in deliverable 5.6),
- a web-based governance survey, which, although not conducted as part of a formal IMI deliverable, was additionally proposed to collect feedback on the study platform governance after one year (as part of WP1 task).

This deliverable provides a detailed overview of the methodology and findings of these various feedback mechanisms.

As of 31 October 2018, invitations to complete the DRIVE communications survey had been issued to 21 representatives of Layer 1 stakeholders with 7 completed surveys received. Respondents indicated additional IVE information they would like to receive, a preference for more frequent communications via a variety of channels and indicated that they intended to share DRIVE results with their own stakeholders. Concerns were raised by 2 respondents – one about the perception of public-private partnerships and the other about the reconciliation of DRIVE IVE results with other national IVE studies.

A total of 68 people representing 34 organisations attended the DRIVE Annual Forum, including pan-European agencies, public health institutes, DRIVE partners, research collaborators and other external stakeholders. The dialogue was both positive and constructive, and focused on the challenges and potential solutions to generating robust brand-specific influenza vaccine effectiveness data in European countries each influenza season. The EMA representative emphasized the importance of ongoing collaboration between public and private partners, and the need for pragmatism in generating and interpreting the data and evolving the approach, particularly in the early stages of the project.

The majority of 2018 Annual Forum attendees participated in the communications workshop. Relevant key themes arising from the communications workshop at the Forum included the importance of transparency, as well as the need for communication to be highly tailored to different stakeholder groups and appropriately sequenced in accordance with a planned timeline. For regulators, the opportunity to review data as it emerges to ensure they are appropriately interpreted before dissemination to other Layer 1 stakeholders was deemed as most important, while for public health institutes complete real-time information about the course of influenza and IVE during each season was seen as most valuable.

A web-based survey about DRIVE governance was issued to all Annual Forum participants, broken down into 4 different groups: external stakeholders, DRIVE partners, the Quality Control and Audit Committee (QCAC) and the Independent Scientific Committee (ISC). The surveys generated 34 responses with varying completion rates in each group. Overall, respondents were positive about

DRIVE and its governance and reinforced the themes raised at the Annual Forum. A key benefit identified by the partners was the opportunity for public and private partners to learn more about each other while most external respondents expressed their interest in joining DRIVE. The surveys reinforced the need to develop further the roles of the advisory committees (QCAC, ISC) and adapt the study platform governance and communication for timeliness and efficient interactions within the consortium.

DRIVE is using the results gleaned from stakeholder feedback to inform and evolve the project and study governance as well as the approach to communications, including choices about content and frequency of communications, and the best communication channels and tools to use for Layer 1 stakeholders. In particular, the results are currently being used to introduce a regular Project newsletter for partners and in the communications planning for the release of the pilot study report. The communications survey will be sent to additional Layer 1 stakeholders and feedback will continue to be sought in other ways throughout the Project as part of a continuous improvement approach.

Introduction

DRIVE has identified a number of different stakeholder groups (see Figure 1) with which it needs to interact and communicate. These have been divided up into Layer 1 and Layer 2 groups (see Figure 1) based on the importance of DRIVE outputs to either fulfilling IVE regulatory requirements or to decision-making with respect to influenza vaccine policy or programmes.

Due to the heterogeneity of stakeholder groups, DRIVE has committed to seeking feedback and guidance from different stakeholder groups about the various aspects of the project including study and project governance and communications.

Feedback has so far been collected via the 2018 DRIVE Annual Forum, including a dedicated communications workshop held at the Forum, a web-based communications survey and a web-based governance survey.

This report details the various methods used to capture Layer 1 stakeholder feedback, the key findings of each type of method used, how the feedback is being used and the intention to continue to solicit feedback throughout the project.

Method

DRIVE Annual Forum

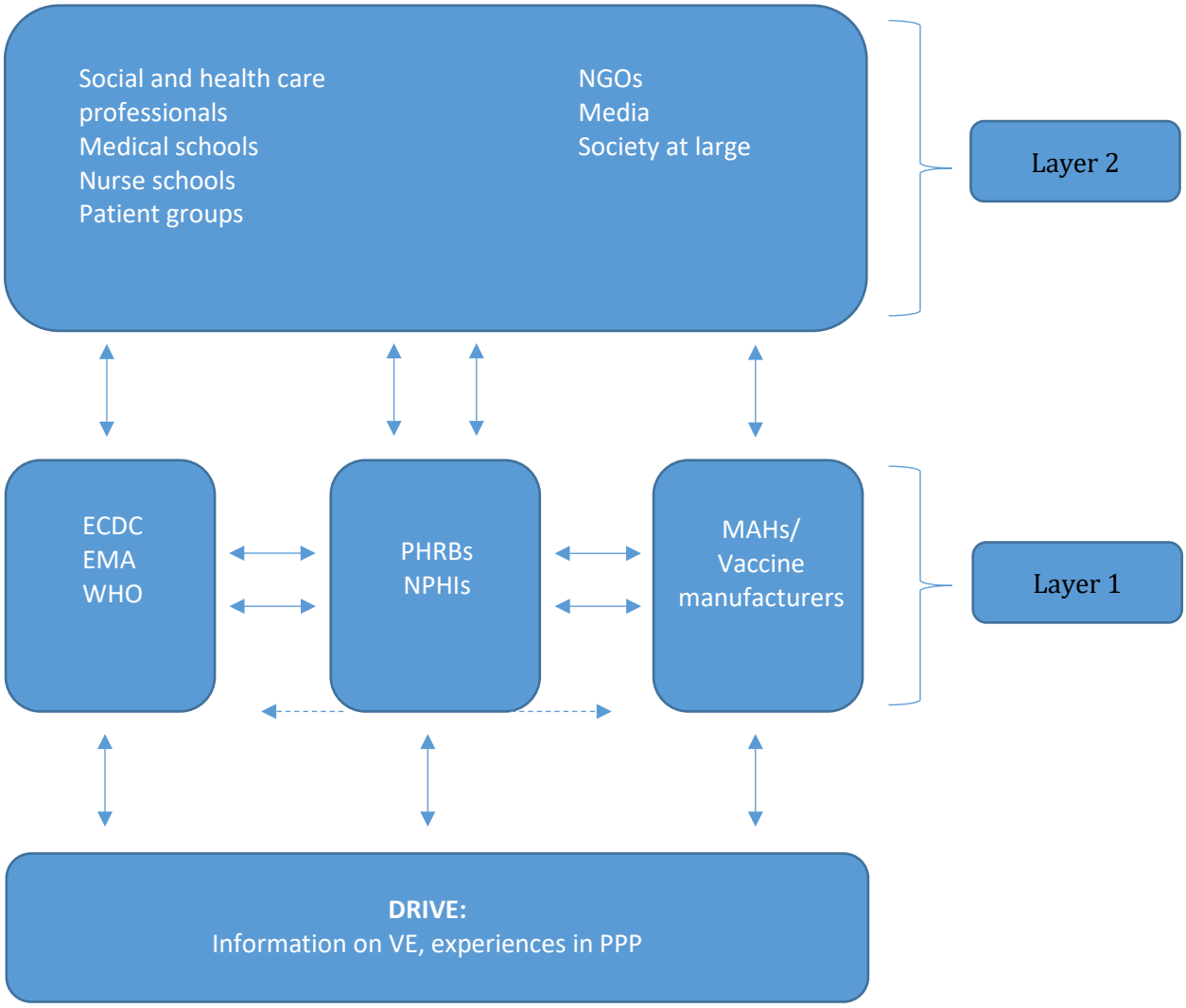
DRIVE held its first Annual Forum in Rome, from 15-17 September 2018 (please refer to D5.6). It was attended by 68 people representing 34 organisations, including pan-European Agencies, DRIVE public and private partners, research collaborators, external stakeholders, members of the Quality Control and Audit Committee (QCAC), the Independent Scientific Committee (ISC) and pan-European agencies. The Forum comprised of a series of presentations on the background to DRIVE and its objectives, the project and study governance, and communications planning. Dialogue took also place in Q&A sessions and workshops which made it possible to capture additional feedback.

Web-based Communications Survey (see Annex 1-3)

Following feedback from the survey pilot (refer D5.3), the final communications survey questions were uploaded to Survey Monkey, an online survey software, and an invitation to participate sent to identified organisations representing the following Layer 1 stakeholders:

- European Centre for Disease Control (ECDC)
- European Commission (Directorate-Generals SANTE and Research and Innovation)
- European Parliament
- National Public Health Institutes

Figure 1 DRIVE Stakeholders



Communications Workshop (See Annex 4)
WP5 took the opportunity to gather further feedback from stakeholders about perceived communications needs through an interactive workshop at the DRIVE Annual Forum. The assumption was that although the annual study results generated by DRIVE should be communicated to a broad audience, the information needed to be adapted for each stakeholder group.

Participants of the Forum were preassigned to one of six different groups representing DRIVE stakeholders: 1) Regulatory authorities; 2) Public health institutes; 3) Researchers and scientists; 4) Health care professionals; 5) Patients and patient associations; and 6) Media.

These six groups were asked to consider the following questions from the point of view of their assigned group and report their findings back to the Forum:

- What do I need to know about the DRIVE findings?
- What am I probably not interested to know in detail?
- When, ideally, do I need to receive the information?
- Why would I be willing to receive the information?

Web-based Governance Surveys (See Annex 5 & 6)

A web-based survey was issued to all Annual Forum participants from 25 September to 8 October with the aim to evaluate the initial study platform governance proposed to conduct the pilot studies during the flu season 2017-18. The survey was designed to target 4 different groups: external stakeholders, DRIVE partners, members of the Independent Scientific Committee (ISC) and members of the Quality Control and Audit Committee (QCAC).

Results

Annual Forum

The Annual Forum generated positive and constructive dialogue about the outputs achieved by DRIVE and the challenges of generating robust effectiveness data for numerous types of influenza vaccines across multiple countries and regions with different policies, coverage and demographics. The EMA representative emphasized the importance of ongoing public and private collaboration as well as practical dialogue between DRIVE and the EMA, particularly in the early stages of the project. A full report of the Annual Forum is detailed in D5.6.

Web-based Communications Survey

As of 25 October 2018, survey invitations had been issued to 21 people representing Layer 1 stakeholders, with 7 completed survey responses received (EC – 2, ECDC – 2, PHIs – 3). A summary of the results are as follows

1. 5 of the 7 of respondents indicated that:
   - They considered current IVE communications received from various sources to be adequate
   - Additional IVE information that would be helpful included: age/risk of influenza vaccine recipients, influenza vaccine type and influenza vaccine brand
2. Nearly all respondents indicated that they would like to receive communications:
   - About DRIVE results and activities frequently,
   - Via direct channels including conferences, publications, direct, news releases, websites and social media
3. All respondents indicated their intention to share DRIVE results with their own stakeholders, mainly through their own publications but also through various other digital and traditional communications channels – most commonly through direct communication, websites and news releases.

4. 2 respondents raised concerns, 1 about Public Private Partnerships and the other about the reconciliation of DRIVE findings with findings of other IVE studies

While the survey responses are limited in number, they provide helpful guidance on communications content, tools and channels that will prove most valuable to Layer 1 stakeholders. Additional survey invitations are planned to be issued and responses will continue to inform DRIVE communications planning.

Questions and responses from the communications survey are set out in Annex 1 & 2 respectively. A more detailed analysis about the country context of each respondent is contained in Annex 3. WP5 will continue to issue the survey to additional layer 1 stakeholders as part of our commitment to continuously improve the way in which DRIVE communicates.

Annual Forum Communications Workshop

Relevant key themes from the workshop included the need for:

- **transparency,** due to perceived negative perceptions about public-private partnerships,
- **communication to be highly tailored,** given the different information needs and levels of technical understanding amongst stakeholder groups
- communications to different stakeholders to be **appropriately sequenced** and undertaken in accordance with **planned timeline**.

The key findings for Layer 1 stakeholders represented in the workshop groups were as follows:

Regulatory Bodies:
DRIVE Influenza Vaccine Effectiveness (IVE) data should be shared with the EMA as it emerges, and periodically, so it can be appropriately reviewed and interpreted before being disseminated and other layer 1 stakeholders. It is not useful to submit irrelevant or statistically not significant results and to burden the system with data that is difficult to interpret. The granularity of the data to be provided requires further discussion.

Public Health Institutes:
PHI's seek complete real-time information on the course of influenza each season, as well as brand-specific IVE for specific risk groups. This is so they can give appropriate advice to health care professionals, the public and policy makers both during an epidemic and in preparation for future seasons. PHIs would also prefer communication to various stakeholders to use an IVE measure of averted cases (positive wording) than percentage effectiveness (negative wording).

The detailed outputs of the workshop by group can be found in Annex 3.

Web-based Governance Surveys

34 out of the 68 people who attended the Annual Forum responded to the survey (50%). The highest response rate was reached among external stakeholders, (13/20, 65%), followed by advisory committee members (2/4, 50%, in each ISC and QCAC) and by DRIVE partners (17/40, 42%). Several groups of stakeholders among 9 EU countries were represented in the survey, mainly Academia & other research institutions, public health institutes, health care providers and vaccine manufacturers.

Overall, respondents were positive about DRIVE and its governance; external stakeholders and DRIVE partners deemed important to provide annual brand-specific influenza vaccine effectiveness (IVE) estimates (100% and 93%, respectively) and answered that public-private collaborations are the best option or one possible good option in 70% and 100% respectively. Current DRIVE study

governance was considered somewhat or completely appropriate by 87% of DRIVE partners, whereas among external stakeholders divergent views emerged, being somewhat or completely appropriate for 5/9 (55%), whereas the other 5 external stakeholders each chose one of the other available options ("not at all appropriate", "not very appropriate", "no opinion/unsure", "the governance is not enough clear for me to respond").
Most of the external stakeholders and the DRIVE partners (89% and 100%, respectively) found the current list of stakeholders appropriate to meet the objectives of the study platform in DRIVE. Two thirds of external stakeholders and 80% of DRIVE partners found the role of the ISC appropriate, and all respondents, except one who expressed no opinion, found that such advisory committee has the required expertise and experience. Most of DRIVE partners (71%) found the role of the QCAC completely or somewhat appropriate, whereas divergent opinions emerged from external stakeholders. More than an half of the external stakeholders (5 /9, 55%) and one ISC member found somewhat or completely appropriate that the sites selection was made by the steering committee composed of 50% public and 50% EFPIA members, compared to 82% among DRIVE partners. However, for the other 4 external stakeholder respondents and one ISC member divergent views emerged (from not at all appropriate to no opinion).

A key benefit identified by the partners was the opportunity for public and private partners to learn more about each other while most external respondents expressed their interest in joining DRIVE. The surveys reinforced the need to develop further the roles of the advisory committees (QCAC, ISC) and adapt the study platform governance and communication for timeliness and efficient interactions within the consortium. The results from the surveys will allow governance monitoring and developing a set of recommendations that will be addressed by the WP1 to the DRIVE Steering Committee that will decide on the implementation of actions, wherever applicable.

A detailed summary of the surveys' results, broken down by stakeholder groups are set out in Annex 5**,** including the surveys questions.

Conclusions

DRIVE has undertaken a number of activities to understand the needs of Layer 1 stakeholders, including an Annual Forum and dedicated communications workshop, a web-based communications survey and web-based Governance surveys.

The results from the different types of feedback mechanisms are being used to inform and evolve the governance and communications approach for DRIVE. In particular, they are currently being used to strengthen study platform governance for the 2018/19 season, introduce an internal newsletter for the consortium and advisory members, and inform communications planning for the release of the pilot year report.

Additional opportunities will continue to be sought throughout the Project to gain feedback from layer 1 stakeholders to ensure DRIVE continues to evolve and meet the needs of stakeholder groups.

Annexes

Annex 1. Web-based communication survey questions

Annex 2. Web-based communication results

Annex 3 Web-based communication survey report

Annex 4 Annual Forum Communications workshop output

Annex 5. Web-based governance survey questions

Annex 6. Web-based governance survey results

Annex 1: Communications survey, questions

DRIVE (Development of Robust and Innovative Vaccine Effectiveness) is a European project under the framework of the Innovative Medicines Initiative (IMI). The goal of DRIVE is to establish a sustainable platform aiming at assessing brand-specific influenza vaccine effectiveness studies in Europe.
The influenza vaccine effectiveness (IVE) results from DRIVE will be publicly disclosed through various channels including reports, peer-reviewed publications, conferences, and through a dedicated website and social media. This survey aims to understand the communication needs and expectations of DRIVE's stakeholders and establish how DRIVE could make its results timely and broadly disseminated.
This survey is intended for experts responsible or involved in in the communication of influenza-related information.
All information collected will be anonymized or pseudo-anonymized and kept in strict confidence among partners within DRIVE consortium and not shared outside of DRIVE without your consent.

1. Please provide your contact details:

Name _____
Organization _____
What is the extent of influence of your organization?
o National
o Regional
o Local
o Other (please specify)_____

Position ____
Address _____
Email _____
Telephone _____

2. Does your organization have a role in communicating information related to influenza surveillance and/or influenza vaccines in your area?
o Yes, we are the main organization responsible.
o Yes, we share the task with other organizations (please indicate who) _____
o No (please indicate who is responsible) _____

3. Please describe your personal role in this communication. Alternatively, please provide contact details of the person responsible for this communication: _____

4. Which of the following local stakeholders does your institution regularly communicate influenza vaccine related information to? (please select all that apply)

□ Social and health care professionals (Please specify names and contact details of organizations)
□ Medical schools (Please specify names and contact details of the schools)
□ Nursing schools (Please specify names and contact details of the schools)

 NGOs (Please specify names and contact details of the schools)_
 Patient groups (Please specify names and contact details of patients groups)_
 Media (Please specify)_____

□ General public
□ Other (Please specify)____
□ None of the above (please provide details; e.g. is there another institution that handles the communications?) _____

5. By what means do you communicate information on influenza vaccines? (please select all that apply)
□ Websites (Please specify)_____
□ Publications (Please specify)_____
□ Scientific posters at conferences
□ Conferences (Please specify)____
□ Public gatherings
□ Direct communication (e.g. email, letter, face to face meeting) (Please specify the target groups of such communication)____
□ Media releases(Please specify)_____
□ Social media (Please specify)_____
□ Other (please specify) _____

6. Do you communicate on the burden of influenza illness?
o Yes
o No

7. Do you communicate on the benefits of influenza vaccines in general?
o Yes
o No

8. Do you communicate on influenza vaccine effectiveness (IVE) results in particular?
o Yes
o No

9. If yes, at what stage (s) of the influenza season do you time your communications? _____

10. What are your sources of information about influenza and/ or IVE? (Please select all that apply)
□ ECDC
□ World Health Organization
□ Ministry of Health___
□ European Medicines Agency
□ National Medicines Agency
□ Scientific literature
□ Other (Please specify)____

11. Is your currently available information on IVE adequate for your needs?
o Yes
o No

12. If not, what additional information on IVE would you require? (e.g. IVE in certain area, in certain age / risk groups, of different vaccine type or brands…)
□ IVE in certain areas

□ IVE in certain age/risk groups
□ IVE of different vaccine type
□ IVE of different vaccine brands
□ Other (Please specify)____

13. In addition to scientific conferences, peer-reviewed publications and the DRIVE website, what other means of communications would you like DRIVE to use to communicate IVE results? (please select all that apply)
□ Scientific posters at conferences
□ Public gatherings (Please specify)_____
□ Direct communication (e.g. email, letter, face to face meeting) (Please specify the target groups of such communication)_____
□ Media releases (Please specify the media) ____
□ Social media(Please specify)_____
□ Other (please specify) _____

14. In what format would you like to receive the results regarding vaccine effectiveness, including the brand specific data results produced by DRIVE? (please select all that apply)
□ Extensive reports with detailed numerical information and discussions of results
□ Condensed and easy to digest abstracts
□ Infographics
□ Other, please specify _____

15. What is your preferred frequency of communications from DRIVE?

□ Yearly, in-depth reports of influenza vaccine effectiveness and DRIVE activities (please provide any specific requests) _____
□ More frequent communications regarding influenza vaccine effectiveness and DRIVE activities; for example using a newsletter (please provide any specific requests) _____
□ Other, please specify _____

16. Which of the following options would you consider using to communicate DRIVE's results to your stakeholders? (please select all that apply)
□ Websites (Please specify)_____
□ Publications (Please specify)_____
□ Scientific posters at conferences
□ Conferences (Please specify)_____
□ Public gatherings (Please specify)_____
□ Direct communication (e.g. email, letter, face to face meeting) (Please specify the target communication groups)_____
□ Media releases (Please specify the media)_____
□ Social media (Please specify)_____
□ Other (please specify) _____
□ No, we would likely not communicate DRIVE's results further (please specify the reasons) _____

17. Do you have any particular concerns about the communication of influenza vaccine effectiveness from DRIVE?
o Yes
o No

18. If you replied “Yes” to question 17, what are your concerns?_____

19. If you replied “Yes” to question 17, what could be done to address these concerns? _____

20. If you have any additional comments, please feel free to write them here_____

21. Do you consent for de-identified and consolidated results from this survey to be shared outside of DRIVE given it

o Yes

o No

o Please provide any specific request you might have_____

Annex 2: Summary of the results from the Web-based Communications Survey

	AUSTRIA	ITALY	FINLAND	VALENCIA	EUROPEAN COMMISSION*	ECDC
Extent of influence of responding organization	National	National	National	Regional	EU 2 different respondents	EU + international
Stakeholders the institution regularly communicate influenza vaccine-related information to	• Social and health care professionals • Media • Medical schools • General public	• Social and health care professionals • Media • General public	• Social and health care professionals • Media • General public	• Social and health care professionals • Media • General public	• Media • General public • Research community, including pharmaceutical industry	• Media • General public • Social and health care professionals • Other
Means used to communicate information on influenza vaccines	Website: www.influenza.at	• Publications (scientific papers on peer reviewed journals) • Conferences (national and international) • Direct communication (weekly report to HCW, the media and the general public) • Media releases • Websites: o Epicentro http://www.epicentro.iss.it/default.asp o ISS http://www.iss.it/ o Italian Ministry of Health http://www.salute.gov.it/portale/home.html	• Publications (e.g. reports, professional magazines, brochures) • Conferences • Direct communication to HCW • Media releases (THL's website, Infectious disease newsletter) • Social media (Twitter, YouTube, Facebook) • Websites: owww.thl.fi/rokottaminen owww.thl.fi/infektiotaudit •Video	• Conferences • Direct communication (e-mail to HCW) • Media releases • Social media, • Publications • Website: www.sp.san.gva.es/rvn	• Publications • Conferences • Direct communication (e.g. email, letter, face to face meeting)	• Conferences • Direct communication • Media releases • Social media • Publications • Websites (ECDC's website and support to EC websites)
Communicate on the burden of influenza Illness	Yes	Yes	Yes	Yes	Yes	Yes

Communicate on the on the benefits of influenza vaccines in general	Yes	Yes	Yes	Yes	Yes	N.A.
Communication IVE results in particular	No	Yes	Yes	No	Yes	Yes
Sources of information about influenza and/or IVE	• ECDC • WHO • Scientific literature • Their own research	• ECDC • WHO • Scientific literature • Ministry of Health • EMA • AIFA (National medicines Agency) • Their own research	• ECDC • WHO • Scientific literature • National real-time data, personal contacts, GIRS • Their own research	• ECDC • WHO • Ministry of Health • Their own research	• ECDC • WHO • EMA • Scientific literature • Projects from our framework programmes on R&I (e.g. FP7, H2020)	• Scientific literature • Their own research • ECDC • Real-time data from THL Finland and Stockholm county
Currently available information on IVE deemed adequate	No	Yes	No	Yes	Yes	No
Additional information on IVE required	• BY age/risk groups • By types • By brand	N. A.	• BY age/risk groups • By types • By brand • By geographic area • By influenza illness severity	N. A.	N. A.	• By type • By age/risk groups • More real-time data
Other means of communications DRIVE should use to communicate IVE results in addition to peer-reviewed	• Conferences • Direct communication (e.g. regular newsletters to DRIVE participants)	• Conferences • Direct communication (periodic newsletter/bulletin)	• Direct communication • Media releases • Social media (Twitter, Facebook, Instagram, YouTube)	• Conferences • Direct communication • Media releases • Social media	• Social media (Twitter, LinkedIn) • Media releases (non-specialized media • Conferences targeting health	• Conferences • Direct communication

publications and DRIVE website					• practitioners and healthcare workers • Direct communication (regular updates on results obtained within DRIVE)	
Preferred format to receive the results regarding IVE, including the brand-specific data results produced by DRIVE	• Extensive reports with detailed numerical information and discussions of results • Condensed and easy to digest abstracts • Infographics	• Extensive reports with detailed numerical information and discussions of results • Condensed and easy to digest abstracts • Infographics	• Extensive reports with detailed numerical information and discussions of results • Condensed and easy to digest abstracts • Infographics	• Extensive reports with detailed numerical information and discussions of results	Infographics Condensed and easy to digest abstracts	• Extensive reports with detailed numerical information and discussions of results • Condensed and easy to digest abstracts Infographics
Preferred frequency of communications from DRIVE	More frequent communications regarding IVE and DRIVE activities; e.g. using a newsletter	More frequent communications regarding IVE and DRIVE activities; e.g. using a newsletter	More frequent communications regarding IVE and DRIVE activities; e.g. using a newsletter	More frequent communications regarding IVE and DRIVE activities; e.g. using a newsletter	More frequent communications regarding IVE and DRIVE activities; e.g. using a newsletter	Yearly, in-depth reports of influenza vaccine effectiveness and DRIVE activities
Availability to communicate DRIVE's results to the respective stakeholders	Yes	Yes	Yes	Yes	Yes	Yes

Options considered to communicate DRIVE's results to stakeholders	Publications	• Publications • Conferences • Direct communication	• Publications • Direct communication • Websites • Media releases • Social media	• Publications • Direct communication Websites • Media releases • Social media • Conferences	• Publications • Direct communication Conferences • Websites • Social media •	• Conferences • Direct communication • Social media
Concerns about the communication of IVE from DRIVE	None	None	None	None	Yes (selected by one of the 2 respondents)	Yes
Consent for de-identified and consolidated results from the survey to be shared outside of DRIVE	Yes	Yes	Yes	Yes	Yes	Yes

Annex 3 – D5.3 Web-based survey amongst layer 1 stakeholders – full report (updated deliverable)

See attached PDF

Annex 4 – Annual Forum Communications Workshop – Outputs

See attached PDF

Annex 5 - Executive summary of web-based Governance surveys

Objective:
With the aim to evaluate its initial study platform governance proposed to conduct the pilot studies during the flu season 2017-18, DRIVE launched 4 anonymous surveys targeting DRIVE Annual Forum (AF) participants. The surveys were run following the AF, from September 25th to October 8th 2018 and directed, respectively at external stakeholders, DRIVE partners, members of the Independent Scientific Committee (ISC) and members of the Quality Control and Audit Committee (QCAC).

Results:
Overall, 68 persons attended the AF were invited to complete the surveys and 34 individual responses were collected (50%). The highest response rate was reached among external stakeholders, (13/20, 65%), followed by advisory members (2/4, 50%, in each ISC and QCAC) and by DRIVE partners (17/40, 42%). Several groups of stakeholders among 9 EU countries were represented, mainly Academia & other research institutions, public health institutes, health care providers and vaccine manufacturers.

- **DRIVE project and governance feedback**

Similar proportions between external stakeholders and DRIVE partners deemed very important or somewhat important (100% and 93%, respectively) to provide annual brand-specific influenza vaccine effectiveness (IVE) estimates. Public-private collaborations (PPC) were deemed the best option or one possible good option by all DRIVE partners and 70% of external stakeholders. Transparency and communication were mentioned as ways to establish more trust around PPC, by 40% of 10 external stakeholders who provided an answer to this question; gathering public/general population opinions, collaborations and management of conflicts of interest were quoted 20% each. Several proposals were made. A similar feedback was collected from DRIVE partners; both groups made several interesting suggestions which will be evaluated for the coming flu season 2018-19.

The explanation provided to AF participants regarding the study governance was completely or somewhat clear for most both among external stakeholders and DRIVE partners, respectively 88.9% and 100%. Current DRIVE study governance was considered somewhat or completely appropriate by 86.7% of DRIVE partners, whereas among external stakeholders divergent views emerged, being somewhat or completely appropriate for 5/9 (55%), whereas the other 5 external stakeholders each chose one of the other available options ("not at all appropriate", "not very appropriate", "no opinion/unsure", "the governance is not enough clear for me to respond").

- **Study platform feedback**

Most of the external stakeholders and the DRIVE partners (89% and 100%, respectively) found the current list of stakeholders appropriate to meet the objectives of the study platform in DRIVE.

Two third of external stakeholders, and 80% of DRIVE partners found the role of the ISC appropriate, and all respondents, except one who expressed no opinion, found that such advisory committee has the required expertise and experience. The fact that ISC members are reimbursed for travel but not paid for their time is considered mostly or completely appropriate, according, respectively to 87% and 60.0% of DRIVE partners, but only to 67% and 22.2%, respectively, of external stakeholders, and half (1/2) of ISC members.

Most of DRIVE partners (71%) found the role of the QCAC completely or somewhat appropriate, whereas divergent opinions emerged from external stakeholders. QCAC members lamented that so far they have not been sufficiently involved in the project in order for them to adequately perform their tasks. More than half of external stakeholders (55%), but also more than one quarter of DRIVE partners (29 %) could not express an opinion if the expertise and

experience of QCAC members is adequate for their role. The fact that QCAC members are reimbursed for travel but not paid for their time is considered mostly or completely appropriate and sustainable, according, respectively to 79% and 57% of DRIVE partners, but only to 55% and 33%, respectively, of external stakeholders, and half of QCAC members: one of the two respondents of the QCAC reported that in his/her opinion it is not at all sustainable nor appropriate.

More than an half of the external stakeholders (5 /9, 55%) and one ISC member found somewhat or completely appropriate that the sites selection was made by the steering committee composed of 50% public and 50% EFPIA members, compared to 82% among DRIVE partners. However for the other 4 external stakeholders respondents and one ISC members divergent views emerged (from not at all appropriate to no opinion).

- **External stakeholders feedback on joining DRIVE**

The majority of external stakeholders would consider joining DRIVE due to its potential to increase vaccine coverage and to contribute to scientific knowledge. The main concern for those who stated they would probably not join was the independence of the project in terms of governance and links with pharmaceutical companies.

- **DRIVE partners lessons learnt**

After the first year of DRIVE, partners stated that they had benefited from the opportunity to learn from others within the partnership and to contribute their ideas, they had learned more about how partnerships operate and how those organisations within the partnerships work. They also benefited from the external funding supplied and more access to data. The main drawbacks of participation reported were the heavy workload, compared with resources available, the difficulties in sharing information about all the activities taking place within the group and having less control over documents submitted to EMA. Both vaccine manufacturers and public partners commented that they had learned more about how the others operate internally; the resources they have, the regulatory requirements they must adhere to and their levels of expertise.

91% of partners felt that study governance had gone ‘quite well’. Suggested improvements were the introduction of an internal newsletter and procedures for better site selection. One also commented on issues with the firewall. 73% of respondents thought the WP7 studies review document went quite well or very well. There were suggestions to stay more on track with timings and to pay greater attention to detail when submitting deliverables, to provide feedback on documents where comments are made and to harmonise methodology between study sites. 73% of respondents felt that the site selection process had either gone well or very well and one suggested to involved ISC for quality assessment.

73% felt that communication within the study platform had gone well or very well but a few felt that it sometimes fell down, in particular between WPs 5 and 7 and between WP8 and elsewhere. There was a suggestion for more face to face meetings. 73% felt that the study platform works quite well or very well but that it would benefit from a clearer plan to on-board new partners and project management for WP7.

Respondents reported either no or a few conflicts within the study platform, with the same response as to how well resolved these conflicts were. There were suggestions for more face-to-face meetings and to ensure tasks are prioritised in keeping with time resource allocated. Half of respondents felt that efforts to on-board new research collaborators in the study platform had been appropriately carried out. One felt that there should be a clear strategy for each country and a few felt that greater awareness of DRIVE was needed as they hadn’t heard of it in time. There was also one comment that IRD leaving was not clearly communicated.

- **ISC lessons learnt**

Only 2 ISC members responded to their survey. The time spent by the ISC members on the DRIVE project varied from 3 to 15 hours per month. Generally speaking the ISC members questioned the work flow and process: they felt that the way it currently works is either inefficient or quite efficient, with difficulties in making comments on EFPIA documents and clearer guidance being required. They felt that they do not receive enough resources to carry out their work in terms of support and access to documents. Problems with document preparation before meetings and awareness of what was taking place within DRIVE were mentioned several times. There were some concerns about the ISC's role in ensuring scientific integrity due to not being kept in the loop and a lack of communication around when input was required.

Only two members of the QCAC answered the survey. They reported spending between 6 and 28 hours per month on DRIVE. Generally speaking the QCAC members questioned the mission and process. They reported having a lack of understanding of what was taking place within the project and a need for a clearer outline of what is expected of them and when. As it stands they find the committee not very efficient. The respondents requested more regular updates so that they could make informed comments and questions and they asked for more members in this committee.

Next steps:
The results from the surveys will allow governance monitoring and developing a set of recommendations by the WP1 to the DRIVE Steering Committee that will decide on the implementation of actions, wherever applicable.

Annex 6 – Web-based Governance Survey – Questions

See attached PDF

D5.3 Web-based survey amongst layer 1 stakeholders

(Updated Report – June 2018)

777363 – DRIVE

DEVELOPMENT OF ROBUST AND INNOVATIVE VACCINE EFFECTIVENESS

WP5 – Communication and dissemination of results

Lead contributor	Miriam Levi (4 – UNIFI), Jari Kirsilä (6 – THL)
	miriam.levi@unifi.it, jari.kirsila@thl.fi
Other contributors	Roberto Bonaiuti (4 – UNIFI)
	Topi Turunen (1 – FISABIO)
	Caterina Rizzo (7 – ISS)
	Sam Rosoman (9 – COMO)
	Laurence Pagnon (12 – SP)
	Sharon McHale (14 – SEQIRUS)

Due date	
Delivery date	
Deliverable type	R
Dissemination level	PU

Description of Work	**Version**	**Date**
	V0.0	01 Dec 2017

Document History

Version	Date	Description
V0.0	15 June 2018	First Draft

Abbreviations

CDC = Centers for Disease Control and Prevention
DRIVE = Development of Robust and Innovative Vaccine Effectiveness
EC= European Commission
ECDC = European Centre for Disease Prevention and Control
EFPIA = European Federation of Pharmaceutical Industries and Associations
EMA = European Medicines Agency
EU = European Union
FISABIO = Fundación para el Fomento de la Investigación Sanitaria y Biomédica de la Comunitat Valenciana
GA = Grant Agreement
IMI = Innovative Medicines Initiative
ISC = Independent Scientific Committee
IVE = Influenza Vaccine Effectiveness
NITAG = National Immunization Technical Advisory Groups
PHRB = Public Health Regulatory Body
PHI = Public Health Institute
SAGE = Strategic Advisory Group on Experts
WHO = World Health Organization
WP = Work Package

1. Publishable Summary

DRIVE carried out a web-based survey using the SurveyMonkey tool (https://surveymonkey.com/r/HKX575N) in order to better understand the communications needs of its stakeholders.The survey was directed at the "level 1" stakeholders identified in deliverable 5.1 ("Communication of a detailed stakeholder map for the DRIVE project, including the identification, grouping and layering of all stakeholders"). The survey was preliminary pilot-tested by the National Influenza Centre of Austria (at Medizinische Universität Wien), that confirmed its participation in DRIVE by May 2018, and subsequently administered to public health institutes (PHIs) already participating in DRIVE, namely Finland, Italy and the Valencia Region in Spain. The topics investigated by means of the survey (available in **Annex 1**) included the content and frequency of DRIVE communications, and the best communication channels to reach its stakeholders.

Findings from the survey are the following. In the opinion of stakeholders, to communicate IVE results DRIVE should use direct communication such as regular email newsletter to DRIVE participants and periodic newsletter/bulletin, conferences, social media (e.g. Twitter, Facebook, Instagram and YouTube) and media releases.

Extensive reports with detailed numerical information and discussions of results should be accompanied by condensed and easy to digest abstracts and infographics in frequently communicating influenza vaccines effectiveness (IVE) and DRIVE activities.

All participating organizations considered communicating results from DRIVE to their respective stakeholders. None of the participating organizations had any particular concerns about the communication of IVE results from DRIVE, and all gave consent for de-identified and consolidated results from the present survey to be shared outside of DRIVE.

2. Methods

A survey was prepared by a small working group within WP5 and circulated for feedback according to the policy described in deliverable D5.2 ("Agreement on communications governance model"). The survey was then administered online using the SurveyMonkey tool (https://surveymonkey.com/r/HKX575N) to the "level 1" stakeholders identified in deliverable 5.1 ("Communication of a detailed stakeholder map for the DRIVE project, including the identification, grouping and layering of all stakeholders").
The survey was preliminary pilot-tested by the National Influenza Centre of Austria (at Medizinische Universität Wien), that confirmed its participation in DRIVE by May 2018, and subsequently administered to public health institutes (PHIs) already participating in DRIVE, namely Finland, Italy and the Valencia Region in Spain, and to the European Commission, some of the "layer 1 stakeholders" identified in deliverable 5.1.

In the next and following years, the survey will be administered to public health institutes and other Associate Partners and research Collaborators of DRIVE that will submit their proposal for the DRIVE call for tenders and that will be selected to participate in DRIVE, as well as to other relevant stakeholders that were identified during the preparation of deliverable D5.1 "Communication of a detailed stakeholder map": e.g. ECDC, EMA, WHO, Strategic Advisory Group on Experts (SAGE), WHO Europe, National Public Health Regulatory Bodies (PHRBs), Manufacturing Authorisation Holders (MAHs)/vaccine manufacturers, DG Santé, National Immunization Technical Advisory Groups (NITAGs).

3. Results

3.1 Summary of characteristics of organizations participating in the survey, by country/region

As for Austria, the Center of Virology, Medical University Vienna participated in the survey; for Italy the Istituto Superiore di Sanità (Rome), for Finland the National Institute for Health and Welfare (THL,

Helsinki); in the case of all these organizations, the extent of influence is national, as they are the main organizations responsible for communicating information related to influenza surveillance and/or influenza vaccines within their respective countries. For Spain it is the Dirección General Salu Pública Valencia, the main organizations responsible for communicating information related to influenza surveillance and/or influenza vaccines within the Spanish autonomous community of Valencia that participated in the survey; its extent of influence is regional: the Valencia Region is of about 5 million inhabitants.

3.2 Austria

In Austria, Influenza-surveillance data are published on a weekly basis online at www.influenza.at. Published data include recent national and European epidemiologic information, number of virus detections within the scope of the Austrian influenza sentinel network, information on vaccine-match/mismatch, information on NAI-resistant, circulating strains. In addition, that information are sent via e-mail to the subscribers of our weekly e-mail newsletter. Subscriber are mainly physicians, pharmacologists, press, etc.

The Center of Virology, Medical University Vienna regularly communicate influenza vaccine-related information to social and health care professionals, medical schools, media and the general public.

Information on influenza vaccines is communicated through the website www.influenza.at. It comprises the burden of influenza illness and the benefits of influenza vaccines in general, but not the influenza vaccine effectiveness (IVE) results in particular.

ECDC, the World Health Organization (WHO), scientific literature and their own research are Austria's PHI sources of information about influenza and/ or IVE.

Currently available information on IVE is not adequate for Austria's needs. Additional information required is IVE by age groups, IVE of different vaccine types and brands.

3.3 Italy

ISS from the flu season 2000-2001, is responsible of the INFLUNET sentinel surveillance system for influenza syndromes, in Italy. Regions, Reference Laboratories, general practitioners and paediatricians collaborate in the surveillance system, which receives support from the Ministry of Health. ISS coordinates the integration of data deriving from other data sources: virological surveillance, SARI/ICU surveillance, mortality surveillance, data from a participatory internet-based monitoring system, vaccination coverage data. Such data are disseminated through a weekly updated report, for communicating timely information about the burden of disease to health care professionals, the media and the general public. IVE studies have been carried out by the ISS, which was partner of the I-MOVE consortium.

ISS regularly communicate influenza vaccine-related information to social and health care professionals (in particular policy makers of regional and local health authorities and Ministry of Health), the media (TV, newspapers, and radio) and the general public.

Publications on peer reviewed journals, national and international conferences, direct communication (weekly report addressing health care professionals, the media and the general public), media releases and websites (Epicentro: http://www.epicentro.iss.it/default.asp; ISS: http://www.iss.it/ and the Italian Ministry of Health website: http://www.salute.gov.it/portale/home.html) are the means by which ISS communicates information on influenza vaccines.

Information communicated comprises the burden of influenza illness, the benefits of influenza vaccines in general, and IVE results in particular (interim analysis at mid-season and final analysis at the end of the season).

The ECDC, the WHO, Ministry of Health, the European Medicines Agency, the National Medicines Agency, scientific literature and their own research are Italy's PHI sources of information about influenza and/ or IVE.

Currently available information on IVE is adequate for Italy's PHI needs.

3.4 Finland

Finland's' respondent personal role in communicating information related to influenza surveillance and/or influenza vaccines consists in preparing communication plans and implementing them together with substance experts

THL regularly communicate influenza vaccine-related information to social and health care

professionals, the media and the public.
Publications (reports, professional journals, brochures), conferences (e.g. targeting GPs and infectious disease physicians/public health nurses/ nurses and doctors working in child welfare clinics), direct communication targeting health care professionals and physicians, media releases, THL's website (www.thl.fi/rokottaminen and www.thl.fi/infektiotaudit), infectious disease newsletter, and social media (Twitter, YouTube, Facebook) are the means by which THL disseminates information on influenza vaccines.
Information communicated comprises the burden of influenza illness, the benefits of influenza vaccines in general, and IVE results in particular. The latter are disseminated as soon as findings to allow for reliable estimation of IVE become available.
Besides the ECDC, the WHO, scientific literature and their own research, including national real-time data, personal contacts, WHO's Global Influenza Surveillance and Response System (GISRS) are Finland's PHI sources of information about influenza and/ or IVE.
Currently available information on IVE is not adequate for Finland's needs; additional information required is IVE by age groups, geographic area, IVE of different vaccine types and brands and IVE according to severity of influenza.

3.5 Valencia Region

The Valencia Region's respondent personal role in communicating information related to influenza surveillance and/or influenza vaccines consists in the design and management of communication strategies in Valencia Region.
Regular communication of influenza vaccine-related information targets social and health care professionals, the media and the public. Each year, before the start of the vaccination campaign, the General Directorate of Public Health of the Valencia Region organizes meetings with health professionals, those responsible for elderly care centres, and with professional and patients associations aimed at sharing the results of the previous vaccination campaign and at informing about the characteristics of the following one.
Publications, conferences, direct communication (e.g. emails, targeting health care professionals working in the national health system), media releases, social media, the website of the General Directorate of Public Health of the Valencia Region (www.sp.san.gva.es/rvn), are the means by which the Valencian General Directorate of Public Health disseminates information on influenza vaccines. Information communicated comprises the burden of influenza illness, the benefits of influenza vaccines in general.
The European Centre for Disease Prevention and Control, the World Health Organization, the Ministry of Health, as well as their own research, are the main sources of information about influenza and/ or IVE.
Currently available information on IVE is deemed adequate.

3.6 European Commission

The European commission (EC)'s role in communicating information related to influenza surveillance and influenza vaccines to the general public, the media and the research community, including the pharmaceutical industry, in the EU is shared with DG SANTE and ECDC, and is realized through workshops, conferences, publications and direct communication (e.g. email, letter, face to face meeting). Discussion on influenza vaccine research and development largely takes place within the Global Funders Consortium for Universal Influenza Vaccine Development (https://unifluvac.org/) and GloPID-R (https://www.glopid-r.org/). Information communicated comprises the burden of influenza illness, the benefits of influenza vaccines in general, and IVE results in particular. The latter are disseminated concomitantly with EC research programmes or policy activities. In particularly heavy influenza seasons or seasons with notably high or low IVE, the EC would discuss the findings as soon as they are available. Mid-season estimates or estimates as soon as possible in the case of a serious outbreak would be very valuable for the EC to know early if additional research efforts or other responses are needed. The EC sources of information about influenza and IVE are ECDC, the World Health Organization, the European Medicines Agency, as well as scientific literature and projects from EC's framework programmes on R&I (e.g. FP7, H2020).

3.7 ECDC

The ECDC role in communicating information related to influenza surveillance and influenza vaccines to the general public, the media and social and health care professionals is realized through, conferences, publications (peer-reviewed publications in the fields of influenza, vaccines and public health. Technical reports on ECDC's website), direct communication (through emails, ECDC extranet, European Influenza Surveillance Network, annual influenza surveillance meetings), media releases (on request/need), social media (continuous monitoring and communications on twitter @ecdc_flu) and websites (ECDC's website and support to EC websites).
Information communicated comprises the burden of influenza illness and on IVE results in particular. The latter are disseminated as soon as robust data/results are available. The ECDC sources of information about influenza and IVE are ECDC, their own research, scientific literature and real-time data from THL Finland and Stockholm county.

Characteristics of organizations participating in the survey are summarized in Table **1**.

3.8 Stakeholders perceived needs regarding communication of DRIVE results

Currently available information on IVE is not considered adequate for Austria, THL Finland and the ECDC (**Table 2**).
In addition to peer-reviewed publications and the DRIVE website, other means of communications DRIVE should use to communicate IVE results are conferences (Austria, Italy, Valencia Region, EC, ECDC, the latter mentioning Options for influenza control, ERS, ESWI, WONCA, ESCAIDE), direct communication (all mentioned it), in particular regular email newsletter to DRIVE participants (Austria) and periodic newsletter/bulletin (Italy), social media (according to the European Commission, the Valencia Region and Finland, with EC specifying Twitter and Finland specifying Twitter, Facebook, Instagram and YouTube) and media releases (EC, Valencia Region and Finland).
Extensive reports with detailed numerical information and discussions of results, together with condensed and easy to digest abstracts and infographics are the preferred formats to receive results regarding IVE, including brand-specific data produced by DRIVE according to all survey participants, except Valencia, which deemed sufficient to receive extensive reports with detailed numerical information and discussions of results and did not mention abstract nor infographics, and the EC, that, on the contrary, expressed preference for infographics and condensed and easy to digest abstracts. In addition, Finland also highlighted that videos and infographics should be easily adaptable to the needs of each country, e.g. translating texts into the national language of the respective country.
The preferred frequency of communication is “more frequent communications regarding IVE and DRIVE activities; for example using a newsletter” for all survey participants except ECDC, that would prefer yearly in-depth reports on both results on IVE and other DRIVE activities. However, one of the two EC participants suggested breaking the frequency with an immediate message to points of contact in case of important findings or situations.
All participating organizations consider communicating DRIVE’s results to the respective stakeholders. Publications are the preferred means to communicate DRIVE’s results to stakeholders according to Austria. Italy selected publications, conferences and direct communication (e.g. email, letter, face to face meeting); Finland selected websites, publications, direct communication, media releases and social media. Valencia was aligned with Finland but mentioned conferences as well. The EC would consider to use its website, publications, conferences, social media and direct communication to GloPID-R and the Global Funders Consortium for Universal Influenza Vaccine Development to communicate DRIVE’s results to its stakeholders; One of the two EC respondents would use EC's social media to promote the work of DRIVE/IMI/the EU. The ECDC mentioned conferences, direct communication (emails to distribution lists) and social media
Concerns about the communication of IVE results from DRIVE were expressed by one of the two EC respondent, in whose opinion findings may be scrutinized and criticized on account of the current climate of vaccine hesitancy in Europe (to address such concern he suggested communicating results with clear and transparent indications of where the findings come from and of the independence of the work that generated them), and by the ECDC who expressed the difficulty of reconciling and interpreting possible differences in results, as several research groups in Europe are reporting results on IVE (participation at conferences and meetings would help addressing such concerns).
All gave consent for de-identified and consolidated results from the present survey to be shared

outside of DRIVE.

Stakeholders perceived needs regarding communication of influenza vaccine effectiveness estimates and DRIVE results are summarized in Table 2.

4. Conclusions

The results of the survey will advise DRIVE on topics including the content and frequency of its communications, and the best communication channels to reach its stakeholders.

In the opinion of stakeholders, to communicate IVE results, DRIVE should use direct communication such as regular email newsletter to DRIVE participants and periodic newsletter/bulletin, conferences, social media and media releases.

Extensive reports with detailed numerical information and discussions of results should be accompanied by condensed and easy to digest abstracts and infographics in frequently communicating influenza vaccines effectiveness (IVE) and DRIVE activities.

All participating organizations considered communicating DRIVE's results to the respective stakeholders. None of the participating organizations had any particular concerns about the communication of IVE results from DRIVE, and all gave consent for de-identified and consolidated results from the present survey to be shared outside of DRIVE.

Table 1 Summary of characteristics of organizations participating in the survey, by country/region

	AUSTRIA	ITALY	FINLAND	VALENCIA	EUROPEAN COMMISSION*	ECDC
Extent of influence of responding organization	National	National	National	Regional	EU	EU + international
Stakeholders the institution regularly communicate influenza vaccine-related information to	• Social and health care professionals • Media • Medical schools • General public	• Social and health care professionals • Media • General public	• Social and health care professionals • Media • General public	• Social and health care professionals • Media • General public	• Media • General public • Research community, including pharmaceutical industry	• Media • General public • Social and health care professionals • Other
Means used to communicate information on influenza vaccines	Website: www.influenza.at	• Publications (scientific papers on peer reviewed journals) • Conferences (national and international) • Direct communication (weekly report to HCW, the media and the general public) • Media releases • Websites: ○ Epicentro http://www.epicentro.iss.it/default.asp ○ ISS http://www.iss.it/ ○ Italian Ministry of Health http://www.salute.gov.it/portale/home.html	• Publications (e.g. reports, professional magazines, brochures) • Conferences • Direct communication to HCW • Media releases (THL's website, Infectious disease newsletter) • Social media (Twitter, YouTube, Facebook) • Websites: ○ www.thl.fi/rokottaminen ○ www.thl.fi/infektiotaudit • Video	• Conferences • Direct communication (e-mail to HCW) • Media releases • Social media, • Publications • Website: www.sp.san.gva.es/rvn	• Publications • Conferences • Direct communication (e.g. email, letter, face to face meeting)	• Conferences • Direct communication • Media releases • Social media • Publications • Websites (ECDC's website and support to EC websites)
Communicate on the burden of influenza illness	Yes	Yes	Yes	Yes	Yes	Yes
Communicate on the on the benefits of influenza vaccines in	Yes	Yes	Yes	Yes	Yes	N.A.

general						
Communication IVE results in particular	No	Yes	Yes	No	Yes	Yes
Sources of information about influenza and/or IVE	• ECDC • WHO • Scientific literature • Their own research	• ECDC • WHO • Scientific literature • Ministry of Health • EMA • AIFA (National medicines Agency) • Their own research	• ECDC • WHO • Scientific literature • National real-time data, personal contacts, GIRS • Their own research	• ECDC • WHO • Ministry of Health • Their own research	• ECDC • WHO • EMA • Scientific literature • Projects from our framework programmes on R&I (e.g. FP7, H2020)	• Scientific literature • Their own research • ECDC • Real-time data from THL Finland and Stockholm county

* 2 respondents

Table 2 Stakeholders perceived needs regarding communication on IVE and of DRIVE results

	AUSTRIA	ITALY	FINLAND	VALENCIA	EUROPEAN COMMISSION (2 respondents)	ECDC
Currently available information on IVE deemed adequate	No	Yes	No	Yes	Yes	No
Additional information on IVE required	• BY age/risk groups • By types • By brand	N. A.	• BY age/risk groups • By types • By brand • By geographic area • By influenza illness severity	N. A.	N. A.	• By type • By age/risk groups • More real-time data
Other means of communications DRIVE should use to communicate IVE results in addition to peer-reviewed publications and DRIVE website	• Conferences • Direct communication (e.g. regular newsletters to DRIVE participants)	• Conferences • Direct communication (periodic newsletter/bulletin)	• Direct communication • Media releases • Social media (Twitter, Facebook, Instagram, YouTube)	• Conferences • Direct communication • Media releases • Social media	• Social media (Twitter, LinkedIn) • Media releases (non-specialized media • Conferences targeting health practitioners and healthcare workers • Direct communication (regular updates on results obtained within DRIVE)	• Conferences • Direct communication
Preferred format to receive the results regarding IVE, including the brand-specific data results produced by DRIVE	• Extensive reports with detailed numerical information and discussions of results • Condensed and easy to digest abstracts • Infographics	• Extensive reports with detailed numerical information and discussions of results • Condensed and easy to digest abstracts • Infographics	• Extensive reports with detailed numerical information and discussions of results • Condensed and easy to digest abstracts • Infographics	• Extensive reports with detailed numerical information and discussions of results	• Infographics • Condensed and easy to digest abstracts	• Extensive reports with detailed numerical information and discussions of results • Condensed and easy to digest abstracts

						Infographics
Preferred frequency of communications from DRIVE	More frequent communications regarding IVE and DRIVE activities; e.g. using a newsletter	More frequent communications regarding IVE and DRIVE activities; e.g. using a newsletter	More frequent communications regarding IVE and DRIVE activities; e.g. using a newsletter	More frequent communications regarding IVE and DRIVE activities; e.g. using a newsletter	More frequent communications regarding IVE and DRIVE activities; e.g. using a newsletter	Yearly, in-depth reports of influenza vaccine effectiveness and DRIVE activities
Availability to communicate DRIVE's results to the respective stakeholders	Yes	Yes	Yes	Yes	Yes	Yes
Options considered to communicate DRIVE's results to stakeholders	Publications	• Publications • Conferences • Direct communication	• Publications • Direct communication • Websites • Media releases • Social media	• Publications • Direct communication Websites • Media releases • Social media • Conferences	• Publications • Direct communication Conferences • Websites • Social media •	• Conferences • Direct communication • Social media
Concerns about the communication of IVE from DRIVE	None	None	None	None	Yes (selected by one of the 2 respondents)	Yes
Consent for de-identified and consolidated results from the survey to be shared outside of DRIVE	Yes	Yes	Yes	Yes	Yes	Yes

Annex 1: Communications survey, questions

DRIVE (Development of Robust and Innovative Vaccine Effectiveness) is a European project under the framework of the Innovative Medicines Initiative (IMI). The goal of DRIVE is to establish a sustainable platform aiming at assessing brand-specific influenza vaccine effectiveness studies in Europe.
The influenza vaccine effectiveness (IVE) results from DRIVE will be publicly disclosed through various channels including reports, peer-reviewed publications, conferences, and through a dedicated website and social media. This survey aims to understand the communication needs and expectations of DRIVE's stakeholders and establish how DRIVE could make its results timely and broadly disseminated.
This survey is intended for experts responsible or involved in in the communication of influenza-related information.
All information collected will be anonymized or pseudo-anonymized and kept in strict confidence among partners within DRIVE consortium and not shared outside of DRIVE without your consent.

1. Please provide your contact details:

Name _____
Organization _____
What is the extent of influence of your organization?
- National
- Regional
- Local
- Other (please specify)_____

Position ____
Address _____
Email _____
Telephone _____

2. Does your organization have a role in communicating information related to influenza surveillance and/or influenza vaccines in your area?
- Yes, we are the main organization responsible.
- Yes, we share the task with other organizations (please indicate who) _____
- No (please indicate who is responsible) _____

3. Please describe your personal role in this communication. Alternatively, please provide contact details of the person responsible for this communication: _____

4. Which of the following local stakeholders does your institution regularly communicate influenza vaccine related information to? (please select all that apply)

- ☐ Social and health care professionals (Please specify names and contact details of organizations)
- ☐ Medical schools (Please specify names and contact details of the schools)
- ☐ Nursing schools (Please specify names and contact details of the schools)
- ☐ NGOs (Please specify names and contact details of the schools)_
- ☐ Patient groups (Please specify names and contact details of patients groups)_
- ☐ Media (Please specify)_____

□ General public
□ Other (Please specify)____
□ None of the above (please provide details; e.g. is there another institution that handles the communications?) _____

5. By what means do you communicate information on influenza vaccines? (please select all that apply)
□ Websites (Please specify)_____
□ Publications (Please specify)_____
□ Scientific posters at conferences
□ Conferences (Please specify)____
□ Public gatherings
□ Direct communication (e.g. email, letter, face to face meeting) (Please specify the target groups of such communication)____
□ Media releases(Please specify)_____
□ Social media (Please specify)_____
□ Other (please specify) _____

6. Do you communicate on the burden of influenza illness?
○ Yes
○ No

7. Do you communicate on the benefits of influenza vaccines in general?
○ Yes
○ No

8. Do you communicate on influenza vaccine effectiveness (IVE) results in particular?
○ Yes
○ No

9. If yes, at what stage (s) of the influenza season do you time your communications? _____

10. What are your sources of information about influenza and/ or IVE? (Please select all that apply)
_____
□ ECDC
□ World Health Organization
□ Ministry of Health___
□ European Medicines Agency
□ National Medicines Agency
□ Scientific literature
□ Other (Please specify)____

11. Is your currently available information on IVE adequate for your needs?
○ Yes
○ No

12. If not, what additional information on IVE would you require? (e.g. IVE in certain area, in certain age / risk groups, of different vaccine type or brands…)
□ IVE in certain areas
□ IVE in certain age/risk groups
□ IVE of different vaccine type
□ IVE of different vaccine brands
□ Other (Please specify)____

13. In addition to scientific conferences, peer-reviewed publications and the DRIVE website, what other means of communications would you like DRIVE to use to communicate IVE results? (please select all that apply)
□ Scientific posters at conferences
□ Public gatherings (Please specify)_____
□ Direct communication (e.g. email, letter, face to face meeting) (Please specify the target groups of such communication)_____
□ Media releases (Please specify the media) ____
□ Social media(Please specify)_____
□ Other (please specify) _____

14. In what format would you like to receive the results regarding vaccine effectiveness, including the brand specific data results produced by DRIVE? (please select all that apply)
□ Extensive reports with detailed numerical information and discussions of results
□ Condensed and easy to digest abstracts
□ Infographics
□ Other, please specify _____

15. What is your preferred frequency of communications from DRIVE?

□ Yearly, in-depth reports of influenza vaccine effectiveness and DRIVE activities (please provide any specific requests) _____

□ More frequent communications regarding influenza vaccine effectiveness and DRIVE activities; for example using a newsletter (please provide any specific requests) _____

□ Other, please specify _____

16. Which of the following options would you consider using to communicate DRIVE's results to your stakeholders? (please select all that apply)
□ Websites (Please specify)_____
□ Publications (Please specify)_____
□ Scientific posters at conferences
□ Conferences (Please specify)_____
□ Public gatherings (Please specify)_____
□ Direct communication (e.g. email, letter, face to face meeting) (Please specify the target communication groups)_____
□ Media releases (Please specify the media)_____
□ Social media (Please specify)_____
□ Other (please specify) _____
□ No, we would likely not communicate DRIVE's results further (please specify the reasons) _____

17. Do you have any particular concerns about the communication of influenza vaccine effectiveness from DRIVE?
○ Yes
○ No

18. If you replied "Yes" to question 17, what are your concerns?_____

19. If you replied "Yes" to question 17, what could be done to address these concerns? _____

20. If you have any additional comments, please feel free to write them here_____

21. Do you consent for de-identified and consolidated results from this survey to be shared outside of DRIVE given it

- Yes
- No
- Please provide any specific request you might have_____

DRIVE

Development of Robust and Innovative Vaccine Effectiveness

Stakeholders feedback from Communication workshop at the Annual Forum 2018

DRIVE Work Packet 5

Acknowledgement
DRIVE project has received funding from the Innovative Medicines Initiative 2 Joint Undertaking under grant agreement No 777363, This Joint Undertaking receives support from the European Union's Horizon 2020 research and innovation programme and EFPIA.

Questions addressed during the Workshop

1. What do I need to know about the DRIVE findings?
2. What I am probably not interested to know in detail?
3. When, ideally do I need to receive the information?
4. Why would I be willing to receive the information?
5. From which channel/stakeholder would you like to receive this information/communication?
6. What are the methods considerations?
7. Strengths/limitations
    - Potential bias/confounders
    - Sample size
8. Which estimates are statistically significant?
9. Do they differ between age strata or sub-groups?
10. Which covariates/confounders/effect modifiers?
11. Crude vs Adjusted, Matched analyses
12. WP5 comments

REGULATORY BODIES
1. What do I need to know about the DRIVE findings?

There is no need for DRIVE to engage in communication directly with the national regulatory authorities.

It is very important that whenever the results are emerging, this should be communicated to us (EMA).

Our [EMA] idea is that Vaccines Working Party (VWP) will start looking at the brand-specific outcomes and ensure that everybody is looking at the data in the same way. It is really important that everybody is in the same page – meaning for example that a national institute could interpret the data in different way and then burden EMA with questions.

It is really important that there is no misinterpretation once translating the results from EMA level to national level and other stakeholders. Maybe another round of discussions with the VWP will be necessary at this point.

Group influenza A and influenza B and the differences between trivalent and quadrivalent are maybe not too helpful for regulatory bodies, instead the strain and coverage data are the most relevant information.

It is not useful to submit irrelevant or statistically not significant results and to burden the system with data that is difficult to interpret. This needs further discussion with the regulators themselves.

It would be good to submit data periodically but to discuss which granularity is relevant.

Conclusion: DRIVE should establish contact the VWP before end of the year.

Public Health Institutions
1. What do I need to know about the DRIVE findings?

PHI's should have a good and complete overview on the course of an influenza epidemic and the effectiveness of influenza vaccination in order to inform stakeholders as the public, professionals and policy makers. PHI's need to have also real-time overview to take action during an epidemic, if necessarily, and at the end of an epidemic to evaluate and prepare for the next season. This information can be obtained from national and international sources; PHI should address and summarize the results obtained from different studies (of sufficient quality).

Communication is always two-way and PHI's should not only send information, but also receive information from their stakeholders.

PHI should have knowledge on the influenza vaccine effectiveness (IVE) in severe influenza cases in the target groups for vaccination, in specific risk groups and by vaccination type. Information on brand specific IVE is important for advise on future purchases (but this is not always the responsibility of PHI).

Communication on IVE by PHI to media, policy makers, clinicians would preferably focus on the number of averted cases (positive wording) instead of percentage effectiveness (negative wording).

Researchers and Scientist
1. What do I need to know about the DRIVE findings?

The vaccine effectiveness estimates should be communicated transparently and with limited constraints.

We need to reinforce the scientific communication with a starting reference for DRIVE. We could produce a statement paper describing what are the objectives of DRIVE. This paper could be quoted at later communications.

For scientists it is important knowing the details of the science behind is. They want to know about the study design, analyses, virology – in short, how did they get to this result?

Health Care Professionals
1. What do I need to know about the DRIVE findings?

The flu burden and about the averted number of cases should be discussed, as these are easier to communicate to wider audience. Both overall cases averted as well as averted hospitalizations and averted deaths should be discussed. These topics are easy to understand, giving tools for HRC professionals to better communicate the important of vaccination and reinforce existing recommendations.

As the is difficulties with the interpretation of the results it is important we put everything in context.

Regarding IV brands; important to communicate also straight to HRC, as in some countries physicians can pick brands. Anyhow DRIVE should not make comparisons between brands.

We should also be clear that when confidence intervals overlap, there is no difference between the vaccines.

It is important to clearly communicate regarding the vaccine type effectiveness.

It is important that evidence-based results are communicated, as spreading results of which we are not sure would only generate confusion and reduce DRIVE credibility.

Patients & Patients Associations
1. What do I need to know about the DRIVE findings?

Vaccine efficacy is complicated, so we need to make sure that we communicate also about:

- Awareness of severity of influenza

- Potential complications of influenza

- Associated benefits of vaccinations.

Also important to consider the ways the information is organised; by age or at risk groups etc.

Valuable to have 2 way communication; what information are people interested in hearing? Should we circulate a survey to POs to find out?

It needs to be discussed what happens if DRIVE receives questions relating to safety? We need to flag up that it is outside of project scope and redirect stakeholders to HCPs or POs.

Media
1. What do I need to know about the DRIVE findings?

Media needs:

- to have information about what DRIVE is
- information who represents DRIVE in their country and what DRIVE is doing in my country
- how does this help/harm citizens of my country

Media needs I to know the IVE results in simple, understandable numbers: for example 1 person in 5 avoided getting ill, x number of persons avoided being hospitalized, x number of complications and deaths were averted.

Is influenza vaccine cost-effective, how much money is saved? (When people don't have to be in sick leave or hospitalized).

We should make a story/narrative of why DRIVE is needed, why this has not been done before, why we can make it success now. Conclusion: because of this unique European collaboration, we can finally gather enough data and analyze it in order to have better vaccines for us all.

DRIVE needs to have a ready Q&A.

Additional information for background should be offered to media:

Influenza and flu are different

Influenza is severe and can be dangerous even for otherwise healthy people but especially to children and the elderly.

ALL
2. What I'm NOT interested in detail

Regulatory authorities	Public Health Institutes	Researchers /scientists	Health care professionals	Patients & patient organizations	Media
Group influenza A and influenza B and the differences between trivalent and quandrivalent are maybe not too helpful.			Lots of people better off with a simple message in scientific papers due to shortage of time - but the full communication should be made available for those who want know more. From the Public Health perspective – it is difficult if we have low VE as the message of a certain season and that we stop vaccinating (ie ACIP discontinued a programme in the USA).	Short messages, with a link to more detailed information, as some will want to receive more technical information	The organizational details Numbers or graphics that are hard to understand

ALL
3. When, ideally do I need to receive the information?

Regulatory authorities	Public Health Institutes	Researchers /scientists	Health care professionals	Patients & patient organizations	Media
It would be good to submit data periodically to EMA but to discuss which granularity is relevant.	Since DRIVE and I-MOVE are currently the two networks in Europe providing information on IVE, their results should preferable be communicated first to ECDC, who sends them in embargo to PHI for (lets say) 24 hours in order to prepare the communication. It should be avoided that PHI's learn about the results from the networks or through the media first. Scientific debate on the study methods and results from I-MOVE, DRIVE or other studies should be supported by ECDC, eg. at the annual flu meeting, where all member states are invited.	Should we be providing preliminary data and what is the timeline for this? It is very unlikely we can provide relevant data for the Vaccine Composition Meeting (VCM), but we do need to consider what the added value of DRIVE data could be on the VCM.	At the beginning of the vaccine campaign: the flu burden; how many cases, deaths during the previous seasons. At the season peak: burden and interim results. At the end of the season, come up with the results of the season.	It is important to have information continually throughout the season.	Before the next influenza season. We should not reach to general media about the pilot IVE results in order to avoid confusion. Expert media can be targeted even before.

ALL
4. Why would I be willing to receive the information?

Regulatory authorities	Public Health Institutes	Researchers /scientists	Health care professionals	Patients & patient organizations	Media
N/A	N/A	N/A	- It is important and it protects themselves and their patients. - Enables them to better communicate the important of vaccination and reinforce existing recommendations .	To be informed and to be able to make informed decisions (for myself or my family).	Journalists need clicks. Influenza and vaccines are of interest. We should carefully plan the media outreach to avoid misleading headlines.

DRIVE

ALL
5. From which channel/stakeholder would you like to receive this information/communication?

Regulatory authorities	Public Health Institutes	Researchers /scientists	Health care professionals	Patients & patient organizations	Media
Straight communication from the DRIVE project.	Answered at the "when" row.	Communication to scientists outside DRIVE through peer-reviewed publications (because that's where scientists get their information + peer-review adds credibility/validity). There are different platforms and we should be providing open access data. We need to set some sort of guidelines for how scientists should work within DRIVE: - We could have an internal capacity building system where we can receive mutual help and share skills. -This could take the form of internal training. There is a need for papers/data on DRIVE to be peer reviewed to ensure that scientific communications are overseen by the scientists within DRIVE.	It important to reach healthcare workers through periodic bulletins, scientific papers, newsletters, social media.	Receive it by via a PO – as there aren't any flu PO's, could be through chronic disease patient groups, IFA, IAPO etc. Should be communicated in an accessible language. Main channel of communication will be through public health organisations.	We must use all channels to reach the media. Infographics can be given for media to use. We must use "plain" language – meaning not specialist jargon.

DRIVE Governance Evaluation - Survey for External Stakeholders

Introduction to the study platform survey

DRIVE has adopted an initial model for study governance that has been used for the pilot studies in the 2017/18 influenza season. However, the governance will be evaluated throughout the 5-year project and updated as needed.

The evaluation encompasses this survey directed at external stakeholders as well as DRIVE partners and members of its advisory committees at various points during the project.

Following your attendance at the DRIVE Annual meeting or webinars, you have received the presentation pack and this survey for completion. **The survey is anonymous and should take no more than 15 minutes to answer.** Your opinions will be very valuable to DRIVE.

We thank you very much in advance for your time!

Please note that your answers may be used anonymously to study the acceptability of the study platform and to inform future improvements.

DRIVE Governance Evaluation - Survey for External Stakeholders

STAKEHOLDER GENERAL INFORMATION

* 1. Which stakeholder group describes your current organisation?

- ◯ Public Health Institute (European / national / regional)
- ◯ Regulatory Authority (European / national / regional)
- ◯ Academia & other research institutions
- ◯ Healthcare provider or a network of providers
- ◯ Other (please specify)
- ◯ Contract Research Organization (CRO) or Small-Medium Enterprise (SME)
- ◯ Civil Society and patient organisations
- ◯ Vaccine manufacturers

2. In what country is your organization located?

- ◯ Austria
- ◯ Belgium
- ◯ Bulgaria
- ◯ Croatia
- ◯ Cyprus
- ◯ Czech Republic
- ◯ Denmark
- ◯ Estonia
- ◯ Finland
- ◯ France
- ◯ Germany
- ◯ Greece
- ◯ Hungary
- ◯ Iceland
- ◯ Ireland
- ◯ Italy
- ◯ Lithuania
- ◯ Luxembourg
- ◯ Malta
- ◯ Netherlands
- ◯ Norway
- ◯ Poland
- ◯ Portugal
- ◯ Romania
- ◯ Slovakia
- ◯ Slovenia
- ◯ Spain
- ◯ Sweden
- ◯ United Kingdom
- ◯ Other (please specify)

DRIVE Governance Evaluation - Survey for External Stakeholders

STUDY PLATFORM OBJECTIVES

The study platform aims to provide yearly robust brand-specific influenza vaccine effectiveness estimates in Europe, covering different settings and target populations, communicating the results to various stakeholders (mainly public health professionals) and submitting the results to the regulatory agencies as per EMA guidelines requirements.

* 3. How important do you think it is to provide annual brand-specific influenza vaccine effectiveness estimates in Europe?

Not at all important	Not very important	No opinion	Somewhat important	Very important
○	○	○	○	○

Please explain your answer

* 4. Is public-private collaboration necessary to build this kind of study platform?

Not an option	Other better option(s) exist	No opinion	It is one possible good option	Best option
○	○	○	○	○

Please explain your answer

* 5. How can we establish more trust around Public-Private collaborations?

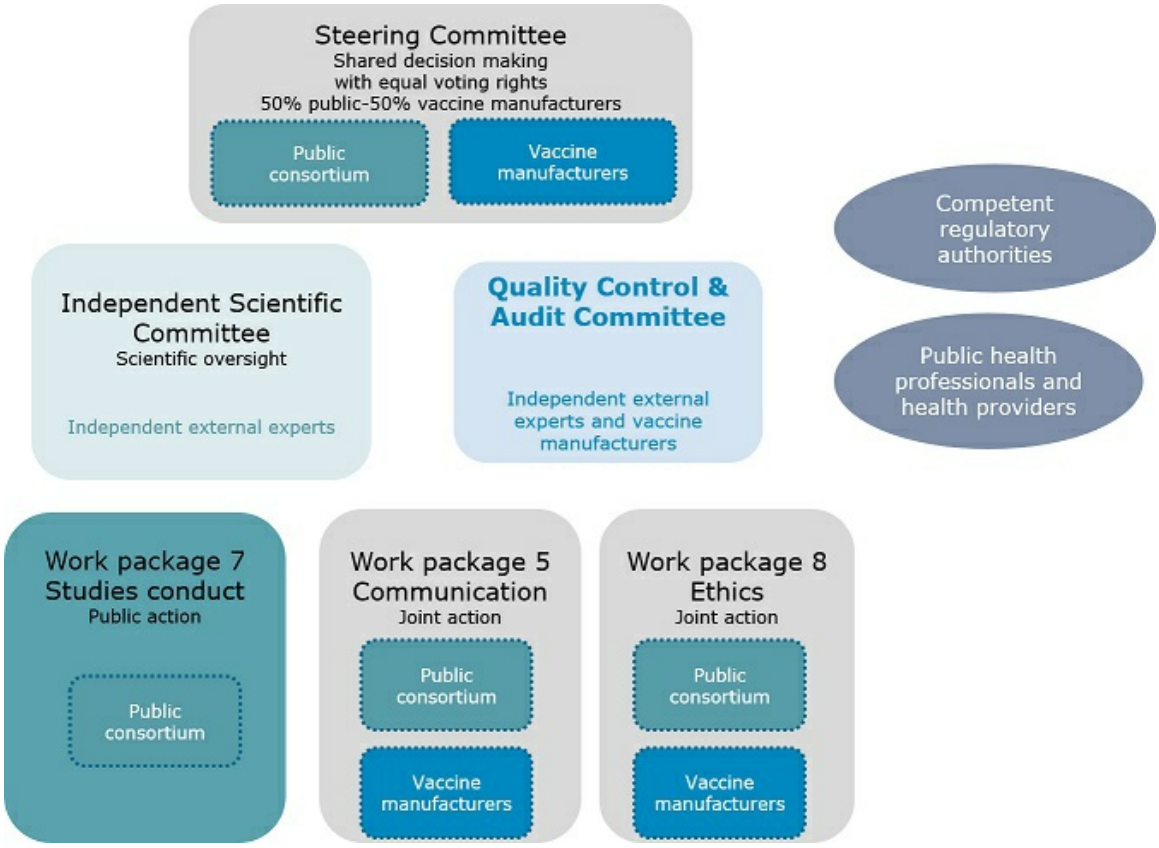
STUDY PLATFORM GOVERNANCE

DRIVE has established specific governance for the study platform to ensure brand-specific influenza vaccine effectiveness studies are scientifically robust, independently conducted and enable partners to fulfil their missions and obligations sustainably.

How it works:

- ***Study design** is carried out by public partners in Work Package 7 (WP7).*
- ***Data collection** is carried out at **several independently operating study sites**. They remain owners of the data they collect and are free to perform site analyses and to publicise their own results.*
- ***New collaborators** are selected by the Steering Committee on a yearly basis through a public call with pre-defined criteria.*
- ***Pan-European pooled analyses** are performed by statisticians and data analysts at P95, a small-medium sized enterprise.*
- ***Study documents** (protocols, statistical analyses, reports and publications) are assessed by the Independent Scientific Committee (ISC). Vaccine manufacturers provide written comments on these documents to the ISC. They are not permitted access to the data or involvement in the conduct of the studies.*
- *The **Quality Control and Audit Committee** advises on compliance and quality of the studies.*
- ***Data quality control and audits** are performed, if required, by a third party on behalf of the vaccine manufacturers to meet their regulatory requirements.*
- ***Ethics requirements** for the study platform are set by public and private partners in Work Package 8 (WP8).*
- *A **pan-European pooled analysis report** is produced at the end of each season by public partners in WP7, with brand-specific influenza vaccine effectiveness estimates. This is jointly submitted by all vaccine manufacturers to competent authorities to fulfil their regulatory obligations.*
- ***Results** are presented in scientific meetings and in peer-reviewed publications by public partners and a summary is published on the DRIVE website. Public and private partners in Work Package 5 (WP5) **communicate** this to public health professionals and health care providers.*

Study platform in DRIVE



* 6. Is the overall explanation you have so far received on the study governance clear for you?

Not at all clear	Not very clear	No opinion or unsure	Somewhat clear	Completely clear
○	○	○	○	○

Please explain (e.g. is there any info missing or unclear?)

* 7. How appropriate is this study governance to provide robust and trusted scientific results?

Not at all appropriate (serious concerns)	Not very appropriate (some concerns)	No opinion / unsure	Somewhat appropriate	Completely appropriate	The governance is not clear enough for me to respond
○	○	○	○	○	○

Please explain (e.g. what would you change, what is appropriate)

* 8. The following stakeholders are currently present within the study platform: *public health institutes, universities, research organisations, small and medium-sized enterprises, patient organisations and vaccine manufacturers*. How appropriate is the list of stakeholders to answer the objectives of the study platform in DRIVE?

Not at all appropriate (serious concerns)	Not very appropriate (some concerns)	No opinion	Somewhat appropriate	Completely appropriate
○	○	○	○	○

Please provide any suggestions and list any stakeholder you think is missing

INDEPENDENT SCIENTIFIC COMMITTEE

The role of the independent scientific committee is to ***evaluate and endorse the studies documents*** *developed by the public partners in Work Package 7.*

The selection of those experts was managed by the Steering Committee using a transparent and documented process. The selection was based on predefined criteria, including relevant expertise in the areas of influenza vaccine effectiveness evaluation; statistics; influenza strain surveillance; vaccination programs; observational and database research; and clinical practice or previous experience working in European or international academic institutions, public health organizations or regulatory agencies. The experts should not have had recent affiliation with any of the DRIVE partners.

The 5 members of the independent scientific committee are namely: ***Hector Izurieta, Liz Miller, Mark Miller, Stefania Salmaso and Marianne van der Sande.*** ***[ISC Members CVs]***

The independent scientific committee members are not paid for their service but are reimbursed for meetings and associated travel expenses.

* 9. Do you think the role of the **Independent Scientific Committee** is appropriate?

Not at all appropriate (serious concerns)	Not very appropriate (some concerns)	No opinion / not sure	Somewhat appropriate	Completely appropriate	The role is not clear enough for me to respond
○	○	○	○	○	○

Please explain your answer

* 10. In your opinion, do the members of the independent scientific committee have the required expertise and experience?

Not at all (serious concerns)	Not enough (some concerns)	No opinion	Mostly	Completely
○	○	○	○	○

Please provide any suggestions for additional or alternative expertise and experience:

* 11. Members of the Independent Scientific Committee are reimbursed for travel but not paid for their time. Do you think this is appropriate and sustainable?

	Not at all	Not very	No opinion	Mostly	Completely
Sustainable	◯	◯	◯	◯	◯
Appropriate	◯	◯	◯	◯	◯

Please provide any alternative suggestions

QUALITY CONTROL AND AUDIT COMMITTEE

*The main role of the quality control and audit committee is to **advise on the compliance and quality of the influenza vaccine effectiveness studies** conducted within the platform. Whenever needed, data quality control and **onsite audit will be performed by a third party** on behalf of the committee to meet vaccine manufacturers' regulatory obligations. The committee is also expected to provide advice on the study platform governance.*

The selection of those experts was managed by the Steering Committee using a transparent and documented process. The selection was based on predefined criteria including relevant expertise and experience in the areas of quality processing, compliance, medical governance, study auditing, and observational study conduct. The composition of the committee was balanced between vaccine manufacturer experts (partners of DRIVE) and independent external experts (who should not have had recent affiliation with any of the DRIVE partners).

*The 4 members of the quality control and audit committee are namely: **Jaime Ballester, Claire Pope, Ann-Marie Kirby and Nathalie Lavis.** **[QCAC members CVs]***

The quality control and audit committee members are not paid for their service; independent external experts are reimbursed for meetings and associated travel expenses.

* 12. Do you think the role of the Quality control and Audit Committee is appropriate?

Not at all appropriate (serious concerns)	Not very appropriate (some concerns)	No opinion / not sure	Somewhat appropriate	Completely appropriate	The role is not clear enough for me to respond
○	○	○	○	○	○

Please explain your answer

* 13. In your opinion, do the members of the quality control and audit committee have the required expertise and experience?

Not at all (serious concerns)	Not enough (some concerns)	No opinion	Mostly	Completely
◯	◯	◯	◯	◯

Please provide any alternative or suggestion

* 14. Independent external experts of the quality control and audit committee are reimbursed for travel but not paid for their time. Do you think this is appropriate and sustainable?

	Not at all	Not very	No opinion	Mostly	Completely
Sustainable	◯	◯	◯	◯	◯
Appropriate	◯	◯	◯	◯	◯

Please provide any alternative or suggestion

INCREASING THE STUDY PLATFORM

Throughout the 5 year project, DRIVE will continue searching for new collaborators (national and regional public health institutes, academic institutions, healthcare provider or a network of providers) with the capacity to perform influenza vaccine effectiveness studies.

- *Public health institutes (regional or national) and other institutions who work on influenza vaccine effectiveness (IVE) are welcome to join the DRIVE project as **Associate Partners**, preferably for the duration of the project.*
- *Starting from the season 2017/18, **Research Collaborators** will be invited for each influenza season through a public call for proposals to fill identified data gaps.*

* 15. For the first call for tender, the selection of study sites was made by the steering committee (50% public and 50% EFPIA) using pre-defined criteria and a transparent process. Do you think this is appropriate within the DRIVE project?

Not at all appropriate (serious concerns)>	Not very appropriate (some concerns)	No opinion or don't know	Somewhat appropriate	Completely appropriate
◯	◯	◯	◯	◯

Please explain or provide any alternatives/suggestions

* 16. Does your organisation have the capacity to share data or carry out influenza vaccine effectiveness studies?

- ◯ No
- ◯ Yes
- ◯ Don't know

The following questions relate to joining DRIVE. **Note that you are under no obligation to join DRIVE if you answer yes; this is purely for us to gauge interest levels.**

* 17. Are you or your organisation interested in joining DRIVE?

Never (serious concerns)	Probably not (some concerns)	No opinion or don't know	Possibly	Yes
○	○	○	○	○

What are your reasons?

* 18. What do you see as potential benefits of joining DRIVE?

* 19. What do you see as the potential drawbacks of joining DRIVE?

GENERAL COMMENT

20. Please provide any further comments

DRIVE Governance Evaluation - Survey for DRIVE partners

Introduction to the study platform survey

DRIVE has adopted an initial model for study governance that has been used for the pilot studies in the 2017/18 influenza season. However, the governance will be evaluated throughout the 5-year project and updated as needed.

The evaluation encompasses this survey directed at external stakeholders as well as DRIVE partners and members of its advisory committees at various points during the project.

The survey is anonymous and should take no more than 15 minutes to answer.

We thank you very much in advance for your time!

Please note that your answers may be used anonymously to study the acceptability of the study platform and to inform future improvements.

DRIVE Governance Evaluation - Survey for DRIVE partners

STAKEHOLDER GENERAL INFORMATION

* 1. Which stakeholder group describes your current organisation?

- ◯ Public Health Institute (European / national / regional)
- ◯ Regulatory Authority (European / national / regional)
- ◯ Academia & other research institutions
- ◯ Healthcare provider or a network of providers
- ◯ Other (please specify)
- ◯ Contract Research Organization (CRO) or Small-Medium Enterprise (SME)
- ◯ Civil Society and patient organisations
- ◯ Vaccine manufacturers

2. In what country is your organization located?

- ◯ Austria
- ◯ Belgium
- ◯ Bulgaria
- ◯ Croatia
- ◯ Cyprus
- ◯ Czech Republic
- ◯ Denmark
- ◯ Estonia
- ◯ Finland
- ◯ France
- ◯ Germany
- ◯ Greece
- ◯ Hungary
- ◯ Iceland
- ◯ Ireland
- ◯ Italy
- ◯ Lithuania
- ◯ Luxembourg
- ◯ Malta
- ◯ Netherlands
- ◯ Norway
- ◯ Poland
- ◯ Portugal
- ◯ Romania
- ◯ Slovakia
- ◯ Slovenia
- ◯ Spain
- ◯ Sweden
- ◯ United Kingdom
- ◯ Other (please specify)

* 3. Have you ever been involved in public-private collaborations before?

- ◯ Never ; it is my first time
- ◯ Yes; only once
- ◯ Yes, several times
- ◯ Would rather not say

STUDY PLATFORM OBJECTIVES

The study platform aims to provide yearly robust brand-specific influenza vaccine effectiveness estimates in Europe, covering different settings and target populations, communicating the results to various stakeholders (mainly public health professionals) and submitting the results to the regulatory agencies as per EMA guidelines requirements.

* 4. How important do you think it is to provide annual brand-specific influenza vaccine effectiveness estimates in Europe?

Not at all important	Not very important	No opinion	Somewhat important	Very important
○	○	○	○	○

Please explain your answer

* 5. Is public-private collaboration necessary to build this kind of study platform?

Not an option	Other better option(s) exist	No opinion	It is one possible good option	Best option
○	○	○	○	○

Please explain your answer

* 6. How can we establish more trust around Public-Private collaborations?

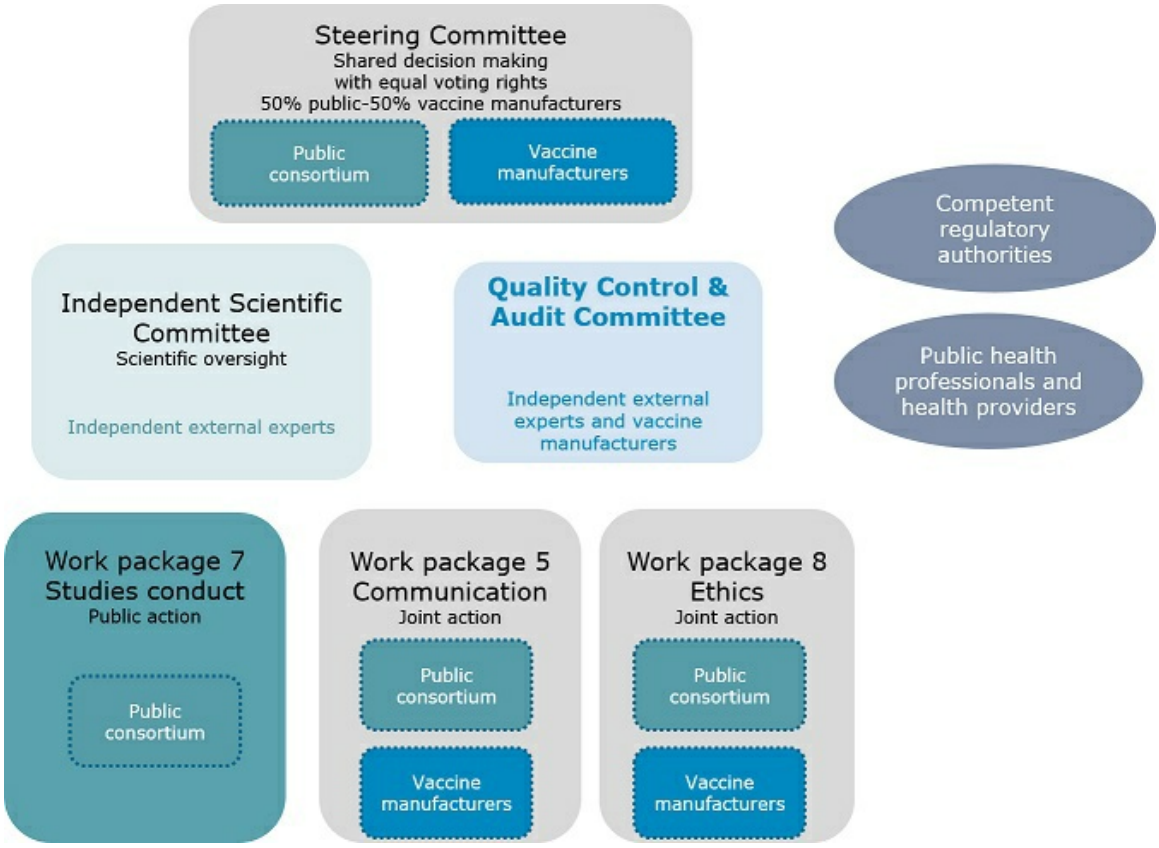
STUDY PLATFORM GOVERNANCE

DRIVE has established specific governance for the study platform to ensure brand-specific influenza vaccine effectiveness studies are scientifically robust, independently conducted and enable partners to fulfil their missions and obligations sustainably.

How it works:

- ***Study design** is carried out by public partners in Work Package 7 (WP7).*
- ***Data collection** is carried out at **several independently operating study sites**. They remain owners of the data they collect and are free to perform site analyses and to publicise their own results.*
- ***New collaborators** are selected by the Steering Committee on a yearly basis through a public call with pre-defined criteria.*
- ***Pan-European pooled analyses** are performed by statisticians and data analysts at P95, a small-medium sized enterprise.*
- ***Study documents** (protocols, statistical analyses, reports and publications) are assessed by the Independent Scientific Committee (ISC). Vaccine manufacturers provide written comments on these documents to the ISC. They are not permitted access to the data or involvement in the conduct of the studies.*
- *The **Quality Control and Audit Committee** advises on compliance and quality of the studies.*
- ***Data quality control and audits** are performed, if required, by a third party on behalf of the vaccine manufacturers to meet their regulatory requirements.*
- ***Ethics requirements** for the study platform are set by public and private partners in Work Package 8 (WP8).*
- *A **pan-European pooled analysis report** is produced at the end of each season by public partners in WP7, with brand-specific influenza vaccine effectiveness estimates. This is jointly submitted by all vaccine manufacturers to competent authorities to fulfil their regulatory obligations.*
- ***Results** are presented in scientific meetings and in peer-reviewed publications by public partners and a summary is published on the DRIVE website. Public and private partners in Work Package 5 (WP5) **communicate** this to public health professionals and health care providers.*

Study platform in DRIVE



* 7. Is the overall explanation you have received so far on the study governance clear for you?

Not clear	Not very clear	No opinion or not sure	Somewhat clear	Completely clear
○	○	○	○	○

Please explain (e.g. is anything unclear or any information missing?)

* 8. How appropriate is this study governance to provide robust and trusted scientific results?

Not at all appropriate (serious concerns)	Not very appropriate (some concerns)	No opinion / not sure	Somewhat appropriate	Completely appropriate	The governance is not clear enough for me to respond
○	○	○	○	○	○

Please explain your answer

* 9. The following stakeholders are currently present within the study platform: *public health institutes, universities, research organisations, small and medium-sized enterprises, patient organisations and vaccine manufacturers*. How appropriate is the list of stakeholders to answer the objectives of the study platform in DRIVE?

Not at all appropriate (serious concerns)	Not very appropriate (some concerns)	No opinion	Somewhat appropriate	Completely appropriate
○	○	○	○	○

Please provide any suggestions and list any stakeholders you think are missing

INDEPENDENT SCIENTIFIC COMMITTEE

The role of the independent scientific committee is to ***evaluate and endorse the studies documents*** *developed by the public partners in Work Package 7.*

The selection of those experts was managed by the Steering Committee using a transparent and documented process. The selection was based on predefined criteria, including relevant expertise in the areas of influenza vaccine effectiveness evaluation; statistics; influenza strain surveillance; vaccination programs; observational and database research; and clinical practice or previous experience working in European or international academic institutions, public health organizations or regulatory agencies. The experts should not have had recent affiliation with any of the DRIVE partners.

The 5 members of the independent scientific committee are namely: ***Hector Izurieta, Liz Miller, Mark Miller, Stefania Salmaso and Marianne van der Sande.*** ***[ISC Members CVs]***

The independent scientific committee members are not paid for their service but are reimbursed for meetings and associated travel expenses.

* 10. Do you think the role of the **Independent Scientific Committee** is appropriate?

Not at all appropriate (serious concerns)	Not very appropriate (some concerns)	No opinion / unsure	Somewhat appropriate	Completely appropriate	The role is not clear enough for me to respond
○	○	○	○	○	○

Please explain your answer

* 11. In your opinion, do the members of the independent scientific committee have the required expertise and experience?

Not at all (serious concerns)	Not enough (some concerns)	No opinion	Mostly	Completely
○	○	○	○	○

Please provide any suggestions for additional or alternative expertise and experience

* 12. Members of the Independent Scientific Committee are reimbursed for travel but not paid for their time. Do you think this is appropriate and sustainable?

	Not at all	Not very	No opinion	Mostly	Completely
Sustainable	◯	◯	◯	◯	◯
Appropriate	◯	◯	◯	◯	◯

Please provide any alternatives or suggestions

QUALITY CONTROL AND AUDIT COMMITTEE

*The main role of the quality control and audit committee is to **advise on the compliance and quality of the influenza vaccine effectiveness studies** conducted within the platform. Whenever needed, data quality control and **onsite audit will be performed by a third party** on behalf of the committee to meet vaccine manufacturers' regulatory obligations. The committee is also expected to provide advice on the study platform governance.*

The selection of those experts was managed by the Steering Committee using a transparent and documented process. The selection was based on predefined criteria including relevant expertise and experience in the areas of quality processing, compliance, medical governance, study auditing, and observational study conduct. The composition of the committee was balanced between vaccine manufacturer experts (partners of DRIVE) and independent external experts (who should not have had recent affiliation with any of the DRIVE partners).

*The 4 members of the quality control and audit committee are namely: **Jaime Ballester, Claire Pope, Ann-Marie Kirby and Nathalie Lavis.** **[QCAC members CVs]***

The quality control and audit committee members are not paid for their service; independent external experts are reimbursed for meetings and associated travel expenses.

* 13. Do you think the role of the Quality control and Audit Committee is appropriate?

Not at all appropriate (serious concerns)	Not very appropriate (some concerns)	No opinion / not sure	Somewhat appropriate	Completely appropriate	The role is not clear enough for me to respond
○	○	○	○	○	○

Please explain your answer

* 14. In your opinion, do the members of the quality control and audit committee have the required expertise and experience?

Not at all (serious concerns)	Not enough (some concerns)	No opinion	Mostly	Completely
◯	◯	◯	◯	◯

Please provide any alternative or suggestion

* 15. Independent external experts of the quality control and audit committee are reimbursed for travel but not paid for their time. Do you think this is appropriate and sustainable?

	Not at all	Not very	No opinion	Mostly	Completely
Sustainable	◯	◯	◯	◯	◯
Appropriate	◯	◯	◯	◯	◯

Please provide any alternatives or suggestions

PARTNER FEEDBACK

* 16. Are you involved in the study platform (are you members of the Steering committee, WP7, WP5 or WP8)?

- ◯ No
- ◯ Yes

The following questions relate to the study platform

* 17. Please describe the benefits to your organisation of taking part in the study platform:

* 18. Please describe the drawbacks to your organisation of taking part in the study platform:

* 19. If you are a public partner, what have you learned from working with the vaccine manufacturer partners? If you are a vaccine manufacturer partner, what have you learned from working with the public partners?

* 20. Generally speaking, how well do you think the study governance has been conducted for the first season?

Not well at all	Not very well	No opinion or I do not have enough information to respond	Quite well	Very well
○	○	○	○	○

Please provide any suggestions for improvements

* 21. How well do you think the WP7 studies review document has been organised for the first season?

Not well at all	Not very well	No opinion or I do not have enough information to respond	Quite well	Very well
◯	◯	◯	◯	◯

Please provide any suggestions for improvements

* 22. How well do you think the sites selection process has been organised for the first tender?

Not well at all	Not very well	No opinion or I do not have enough information to respond	Quite well	Very well
◯	◯	◯	◯	◯

Please provide any suggestions for improvements

* 23. Do you think it is appropriate that the sites selection was made by the steering committee (50% public and 50% EFPIA)?

Not at all appropriate (serious concerns)	Not very appropriate (some concerns)	No opinion or don't know	Somewhat appropriate	Completely appropriate
◯	◯	◯	◯	◯

Please explain or provide any alternative/suggestion

* 24. How well do you think the communication between partners has been managed within the study platform?

Not well at all	Not very well	No opinion or I do not have enough information to respond	Quite well	Very well
◯	◯	◯	◯	◯

Please provide any suggestions for improvements

* 25. Do you think the study platform works efficiently?

Not at all	Not very	No opinion or I do not have enough information to respond	Quite well	Very well
◯	◯	◯	◯	◯

Please provide any suggestions for improvements

* 26. Have you encountered conflicts within the study platform?

Never	Rarely	No opinion or I do not have enough information to respond	A few times	Regularly
◯	◯	◯	◯	◯

Can you give examples of these situations?

27. If you encountered any conflicts, were they well resolved?

Never	Rarely	No opinion or I do not have enough information to respond	Mostly	Always
◯	◯	◯	◯	◯

Please describe what you think went well or what went wrong and please suggest any improvements:

* 28. Do you think efforts to on-board new research collaborators in the study platform have been appropriately carried out in the context of the first year?

Not at all	Not very	Not sure or I do not have enough information to respond	Quite well	Very well
◯	◯	◯	◯	◯

Please provide any suggestions for improvements

GENERAL COMMENT

29. Any other feedback or advice?

DRIVE Governance Evaluation - Survey for Independent Scientific Committee members

Introduction to the study platform survey

DRIVE has adopted an initial model for study governance that has been used for the pilot studies in the 2017/18 influenza season. However, the governance will be evaluated throughout the 5-year project and updated as needed.

The evaluation encompasses this survey directed at external stakeholders as well as DRIVE partners and members of its advisory committees at various points during the project.

Recommendations from this survey will be addressed to the DRIVE Steering Committee, who will decide on implementation of actions where applicable.

The survey is anonymous and should take no more than 15 minutes to answer.

We thank you very much in advance for your time!

Please note that your answers may be used anonymously to study the acceptability of the study platform and to inform future improvements.

DRIVE Governance Evaluation - Survey for Independent Scientific Committee members

GENERAL INFORMATION

* 1. Why did you accept to join the DRIVE Independence Scientific Committee?

* 2. Have you ever been professionally involved with vaccine manufacturers?

- ◯ Yes, by working in the industry
- ◯ Yes, by participating as a public partner in a public-private collaboration
- ◯ Yes, in another way
- ◯ No

If you answered 'yes' above, please provide more details:

DRIVE Governance Evaluation - Survey for Independent Scientific Committee members

COMMITTEE: WORKLOAD AND GOVERNANCE

* 3. How much time do you generally spend on the DRIVE project, on a monthly basis? (please indicate hours per month)

* 4. Based on the time you spend on the project, is it appropriate and sustainable to work with no monetary compensation?

	Not at all	Not very	No opinion	Mostly	Completely
Sustainable	○	○	○	○	○
Appropriate	○	○	○	○	○

Please provide any alternative or suggestion

* 5. Do you feel the ISC members, as a whole, have diverse enough expertise and experience to cover the different tasks of the committee?

Not at all	Not enough	No opinion / don't know	Mostly	Completely
○	○	○	○	○

Please provide any alternative or suggestion

* 6. Do you feel the independent scientific committee works in an efficient way?

Not at all efficient	Not very efficient	No opinion / don't know	Quite efficient	Very efficient
◯	◯	◯	◯	◯

Please provide any alternative or suggestion

* 7. Do you receive sufficient support from the DRIVE project to carry out your work?

Not at all	Not enough	No opinion or don't know	Mostly	Completely
◯	◯	◯	◯	◯

Please provide any alternative or suggestion

* 8. Do you feel you have the access to all relevant DRIVE information to carry out your work?

Not at all	Not enough	No opinion or don't know	Mostly	Completely
◯	◯	◯	◯	◯

Please provide any alternative or suggestion

* 9. How well do you think the review process has been organized for the studies' documents?

Not well at all	Not very well	No opinion or don't know	Quite well	Very well
◯	◯	◯	◯	◯

Please provide any suggestions for improvement

* 10. To safeguard scientific independence of the DRIVE studies, vaccine manufacturers' input on studies has been limited to written comments about the studies documents addressed to the ISC. Does this process ensure adequate scientific independence?

Not at all adequate (serious concerns)	Not very adequate (some concerns)	No opinion or don't know	Partly adequate	Completely adequate
○	○	○	○	○

Please provide any alternative or suggestion

* 11. Based on the pilot season, do you think EFPIA comments were relevant?

Not relevant (serious concerns)	Not very relevant (some concerns)	No opinion or don't know	Partly relevant	Completely relevant
○	○	○	○	○

Please explain your answer

* 12. The independent scientific committee's role also includes advising DRIVE about scientific integrity. Do you feel DRIVE does enough to facilitate this?

Not at all (serious concerns)	Not very (some concerns)	No opinion or don't know	Partly	Completely
○	○	○	○	○

Please provide any alternative or suggestion

* 13. For the first call for tender, the selection of study sites has been made by the steering committee (50% public and 50% EFPIA) using pre-defined criteria and a transparent process. Do you think this is appropriate within the DRIVE project?

Not at all appropriate (serious concerns)	Not very appropriate (some concerns)	No opinion or don't know	Somewhat appropriate	Completely appropriate
○	○	○	○	○

Please explain or provide any alternative or suggestion

STUDY PLATFORM SUSTAINABILITY

DRIVE aims to develop a study platform that would allow brand specific influenza vaccine effectiveness studies to continue after the 5-year project.

* 14. Is it conceivable that a comparable independent scientific committee would continue after the end of the DRIVE project?

Not at all (serious concerns)	Not very (some concerns)	No opinion	Partly	Completely
○	○	○	○	○

Please provide any alternative or suggestion

* 15. What would be required for its sustainability: especially considering the scientific integrity and quality?

GENERAL COMMENT

16. Any other feedback or advice to DRIVE?

DRIVE Governance Evaluation - Survey for Quality Control and Audit Committee members

Introduction to the study platform survey

DRIVE has adopted an initial model for study governance that has been used for the pilot studies in the 2017/18 influenza season. However, the governance will be evaluated throughout the 5-year project and updated as needed.

The evaluation encompasses this survey directed at external stakeholders as well as DRIVE partners and members of its advisory committees at various points during the project.

Recommendations from this survey will be addressed to the DRIVE Steering Committee, who will decide on implementation of actions where applicable.

The survey is anonymous and should take no more than 15 minutes to answer.

We thank you very much in advance for your time!

Please note that your answers may be used anonymously to study the acceptability of the study platform and to inform future improvements.

DRIVE Governance Evaluation - Survey for Quality Control and Audit Committee members

GENERAL INFORMATION

* 1. Why did you accept to join the DRIVE Quality Control and Audit Committee?

* 2. Have you ever been professionally involved with vaccine manufacturers?

- ◯ Yes, by working in the industry
- ◯ Yes, by participating as a public partner in a public-private collaboration
- ◯ Yes, in another way
- ◯ No

If you answered 'yes' above, please provide more details:

COMMITTEE: WORKLOAD AND GOVERNANCE

* 3. Do you think the role of the Quality control and Audit Committee is appropriate?

Not at all appropriate	Not very appropriate	No opinion	Somewhat appropriate	Completely appropriate
◯	◯	◯	◯	◯

Please explain your answer

* 4. How much time do you generally spend on the DRIVE project, on a monthly basis? (please indicate hours per month)

* 5. Is it appropriate and sustainable for independent external experts to work with no monetary compensation?

	Not at all	Not very	No opinion	Mostly	Completely
Sustainable	◯	◯	◯	◯	◯
Appropriate	◯	◯	◯	◯	◯

Please provide any alternative or suggestion

* 6. Do you feel the Quality Control and Audit Committee members, as a whole, have diverse enough expertise and experience to cover the different tasks of the committee?

Not at all	Not enough	No opinion or don't know	Mostly	Completely
○	○	○	○	○

Please provide any alternatives or suggestions

* 7. Do you feel the Quality Control and Audit Committee works in an efficient way?

Not at all efficient	Not very efficient	No opinion or don't know	Quite efficient	Very efficient
○	○	○	○	○

Please provide any alternatives or suggestions

* 8. Do you receive sufficient support from the DRIVE project to carry out your work?

Not at all	Not enough	No opinion or don't know	Mostly	Completely
○	○	○	○	○

Please provide any alternatives or suggestions

* 9. Do you feel you have the access to all relevant DRIVE information to carry out your work?

Not at all	Not enough	No opinion or don't know	Mostly	Completely
○	○	○	○	○

Please provide any alternatives or suggestions

STUDY PLATFORM SUSTAINABILITY

* 10. Data used by DRIVE is secondary; while the project offers generic protocols and guidelines, the study sites operate independently without explicit supervision from DRIVE. How does this affect the quality control and audit committee role, in your opinion?

* 11. DRIVE aims to develop a governance platform that would allow brand-specific influenza vaccine effectiveness studies to continue after the 5-year project. Is it conceivable that a comparable quality control and audit committee would continue after the end of the DRIVE project?

Not at all (serious concerns)	Not very (some concerns)	No opinion	Mostly	Completely
◯	◯	◯	◯	◯

Please provide any alternatives or suggestions

* 12. What would be required for its sustainability: especially considering the quality aspects?

GENERAL COMMENT

13. Any other feedback or advice to DRIVE?