5.6 Periodical back to back Forum of Key Stakeholders

777363 – DRIVE

Development of Robust and Innovative Vaccine Effectiveness

WP5 – Communications

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Document History

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V0.2	24 OCT 2018	Second draft
V0.3	24 OCT 2018	Third Draft
V0.4	25 OCT 2018	Fourth Draft
V1.0	8 NOV 2018	Final Version

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Abbreviations

CHMP	Committee for Medicinal Products for Human Use (see also here)
CMD*h*	Co-ordination Group for Mutual Recognition and Decentralised procedures - Human (see also here)
DRIVE	Development of Robust and Innovative Vaccine Effectiveness
ECDC	European Centre for Disease Prevention and Control
EMA	European Medicines Agency
EU	European Union
IMI	Innovative Medicines Initiative
MAH	Marketing Authorisation Holder
MS	Member State
NCA	National Competent Authority
PHI	Public Health Institute
RMS	Reference Member State
VE	Vaccine Effectiveness
VWP	Vaccines Working Party
WP	Work Package

Publishable Summary

The DRIVE consortium has been created to generate brand-specific data on the effectiveness of seasonal influenza vaccines in order to fulfil the requirements described in EMA guideline on influenza vaccines (https://www.ema.europa.eu/documents/scientific-guideline/influenza-vaccines-non-clinical-clinical-module_en.pdf).

Addressing this new requirement through a public-private partnership, and by collaborating with public health partners who have existing infrastructure in place, is considered key to enhancing the EU/EEA capacity to generate robust brand-specific influenza vaccine effectiveness (IVE) data and to increase the overall understanding of influenza vaccine performance.

The public-private collaboration, however, comes with specific considerations for the study and communication of IVE, as well as the submission of the IVE estimates to the EU regulatory authorities. In addition, and separate from the procedural obligations of the MAHs related to their product licenses, DRIVE recognizes the need for broader scientific discussion with EMA and relevant regulatory authorities on understanding IVE as well as on the feasibility of and experience with the implementation of the guidance.

To facilitate review and feedback of the scientific progress of DRIVE and to help plan ahead, DRIVE has committed to conduct an Annual Forum. The first Annual Forum was held in Rome on 17-18 September. It was attended by 34 organisations, including public and private partners, collaborating institutions, as well key pan-European stakeholders in the EMA, ECDC and IMI. Visibility generated by the Annual Forum attendees through social media provided an indicator of positive engagement.

There was constructive discussion 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, and to communicating results in a meaningful and responsible way. EMA reinforced the importance of ongoing public and private collaboration and practical dialogue to achieve the aims of DRIVE. Guidance on how to best tailor the communication of IVE to different stakeholder groups was also captured.

The outputs of the Annual Forum will be valuable in strengthening collaboration, communication and the overall approach to DRIVE.

1. Introduction

The DRIVE consortium has been created to generate brand-specific data on the effectiveness of seasonal influenza vaccines in order to fulfil the requirements described in EMA guideline on influenza vaccines (https://www.ema.europa.eu/documents/scientific-guideline/influenza-vaccines-non-clinical-clinical-module_en.pdf), and to provide this information to other stakeholders who are mandated to develop influenza vaccination policy and/or programmes or guide the use of influenza vaccines, as well those, who need to know of the effectiveness of these vaccines from their personal or institutional perspective.

DRIVE has committed to conducting an Annual Forum to gather feedback from key stakeholders on the scientific progress of the project and to be able to effectively plan ahead. This deliverable describes the agenda and contents of the first DRIVE Annual Forum held in Rome in September 2018, and the feedback obtained from the different participating stakeholders.

2. The Annual Forum

Several work packages collaborated to arrange the logistics of the Annual Forum, develop the Annual Forum agenda, secure guest speakers and prepare the various sessions. The resulting agenda is detailed below:

DRIVE ANNUAL FORUM

17th–18th September 2018

Istituto Superiore Sanitá (ISS)
Via Giano della Bella 34, 00161 Rome
Meeting Room: Aula Rossi (Floor -1)

Topic	Speaker	Time
DAY 1		
Welcome	Javier Díez-Domingo (FISABIO) Cedric Mahé (SP)	**14.00**
Setting the scene: EMA perspective on influenza vaccines	Marco Cavaleri (EMA)	**14.10**
Influenza VE studies in Europe. Current landscape and how did we get here	Pasi Penttinen (ECDC)	**14.55**
Governance in DRIVE • Independent Scientific Committee position on PPP Governance • Quality Control and Audit Committee introduction	Laurence Pagnon (SP) ISC representatives	**15.40**
Coffee break		**16.50**
Lessons learnt from the pilot season 2017/18: Vaccine effectiveness results & study tools developed by DRIVE • Brand specificities • Study tools for improvement (Systematic review on bias & confounding; study support application; framework for data analysis; guidelines for interpreting IVE results) • Results presentation	Chair: Stefania Salmaso (independent) Mendel Haag (SEQIRUS) Gaël dos Santos (GSK) Topi Turunen (FISABIO) Marga Riera (P95) Hanna Nohynek (THL) Caterina Rizzo (ISS)	**17.15**
Networking Cocktail ***Galeone Bistrot* (in front of ISS)** **Via della Lega Lombarda, 53**		**19.30**

DAY 2		
DRIVE communication plan and debate: How to best communicate IVE results?	Hanna Nohynek, Riia Järvenpää (THL) Sharon McHale (SEQIRUS)	**9.00**
Coffee break		**10.40**
Innovative IVE study approaches: proposal and debate	Marga Riera (P95) Anke Stuurman (P95)	**11.00**
Getting involved in DRIVE	Javier Díez-Domingo, Topi Turunen (FISABIO)	**12.20**
Wrap up	Javier Díez-Domingo (FISABIO) Cedric Mahé (SP)	**12.40**
End of the meeting		**13.00**

2.1 Central themes arising from presentation and stakeholder discussions

The Annual Forum was opened with key note introductions from the coordinator of the project, Head of Faculty of FISABIO Vaccine Research, Javier Díez-Domingo and Cedric Mahe, the Associate VP and Head, Vaccine Epidemiology and Modeling of Sanofi Pasteur.

Díez-Domingo presented the foundations of DRIVE: why this kind of project is important especially now. EMA has introduced a new requirement for brand-specific influenza vaccine effectiveness results from the vaccine manufacturers. The aim of these requirements is to provide a better understanding of the effectiveness of different types of influenza vaccines used in Europe.

This regulatory requirement necessitates a new approach to evaluating the effectiveness of seasonal influenza vaccines. In order the provide this information, EMA encourages the industry to liaise with public health authorities who have experience in IVE studies and who have functioning infrastructure to conduct multicentre studies. DRIVE responds to these regulatory and public health needs and is developing a governance model for transparent, scientifically robust studies in public-private partnerships.

Analysing the effectiveness of numerous types of influenza vaccines across multiple countries is not an easy task. Vaccine response differs with population characteristics including age and underlying medical conditions. Also, different strains of the influenza virus may circulate in different times of the season and in different regions of Europe. The vaccine recommendations, coverage and brands used also differ between the EU countries. Furthermore, differences in research methods and the settings where the data is collected means that pooling the data is methodologically challenging.

2.2 Materials presented which can be published in public domain

All the Annual Forum materials which can be shared in public domain are banked on the DRIVE website at www.drive.org and SlideShare to ease the access and use of them. These are listed and included in Annex 1.

2.3 Communications group work outputs

WP5´s contribution to the Annual Forum was to arrange an interactive group work session where participants were preassigned to 6 groups to represent different stakeholders, i.e. 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 points:

- What do I need to know about the DRIVE findings?
- What I am 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?

The research group answered also specific questions regarding the methodology:

- From which channel/stakeholder would you like to receive this information/communication?
- What are the methods considerations? Strengths/limitations- Potential bias/confounders - Sample size
- Which estimates are statistically significant?
- Do they differ between age strata or sub-groups?
- Which covariates/confounders/effect modifiers?
- Crude vs Adjusted, Matched analyses
- In the plenary feedback part of the group work, WP5 members but also others commented to each group´s synopsis.

The workshop output highlights that the different stakeholders have different needs and expectations – and that results have to be disseminated according to a planned timeline. The timeline had been already developed and presented at the Annual Forum, and the insight gained during the workshop further emphasizes its importance.

The results will be disseminated to EU-level organizations first, and before releasing the results to public domain EMA and ECDC will be given time to analyse the results and communicate directly to their national counterparts.

Transparency is one of the cornerstones of DRIVE's communication strategy. The results will be published on the DRIVE website and social media. Also, media will be engaged when suitable, but the media outreach will carefully be planned to avoid misleading headlines.

Public health institutes, patient organizations and media would need also information on the burden of disease and cases averted by vaccination. Anyhow as studying the burden of disease is not an objective of DRIVE, we should refer to sources as ECDC when communicating to these layer 2 stakeholders.

The detailed outputs of the groups can be found in Annex 2.

2.4 Participating institutions

In total 34 organisations were represented at the Annual Forum.

Twenty represented public health institutes (PHI) or public partners: 10 from present DRIVE partner institutes, four from to-be-come partner institutes whose applications for DRIVE studies were accepted for the second project year; and six from other interested PHIs and/or public partners.

Three pan-European institutes were represented: ECDC, EMA and IMI.

A detailed list of participants cannot be made publicly available due to general data protection regulations.

2.5 Visibility of the Annual Forum in social media as an indicator of success

The visibility generated for DRIVE and the Annual Forum through social media reinforced the key themes – the DRIVE model and the pilot year's experiences – and indicated positive engagement with participating stakeholders.

A total of 173 posts to Twitter using the hashtag #DRIVEflu were published at the period of September the 7th to September the September the 25th. The #DRIVEflu hashtag is used in Twitter to gather the conversations related to DRIVE in one thread. Tweets using the DRIVE's hashtag were written by 51 different accounts. The most widely seen tweet with the hashtag #DRIVEflu was published by Sanofi Pasteur.

The top tweet by DRIVE Twitter account gained over 5000 impressions. This means that the tweet was shown more than 5000 times on Twitter-users devices. The top tweet mentioning DRIVE was made by Mónica Vázquez-Moreno (FISABIO), and that one gained 65 interactions (meaning the tweet was clicked 65 times). Several key stakeholders engaged in Twitter with DRIVE during the Annual Forum.

Twitter Analytics sheet can be found of Annex 3.

3. Conclusions

The Annual Forum discussion concentrated on different aspects of how to tackle the challenge of analysing brand-specific influenza vaccine effectiveness. Some of the most valuable outputs extracted from the consortium's Annual Forum came from the active and constructive conversations with the public health and regulatory professionals – who will be the end users of the project's results. The challenges of analysing the effectiveness of numerous types of influenza vaccines across multiple countries and regions were discussed at length and potential solutions proposed.

The communication workshops mapped how information must be adapted from one stakeholder group to another. For example, regulatory organizations such as EMA need the brand-specific information and scientists may want to understand the methodology behind the results. Other stakeholders such as clinicians and political decision-makers may appreciate more concrete and accessible information such as the cost-effectiveness of influenza vaccination.

DRIVE has completed a pilot study to test the platform; the feedback at the Annual Forum will help strengthen our approach and we work towards the ultimate goal of generating robust brand-specific influenza vaccine data. In the future, harmonized study protocols and data collection will facilitate more robust IVE estimates and provide better information about the way in which they protect populations in Europe. Feedback from stakeholders will help to tailor the communication about the project outputs for end users of the data.

Annexes

Annex 1. List of Presentations and individual presentations as separate annexes

Annex 2. WP5 group work output

Annex 3. Twitter analytics sheet

Annex 1. List of Presentations and individual presentations (also to be found at www.drive-eu.org and Slideshare)

1. DRIVE Genesis – Cedric Mahe (SP)
2. Introduction to DRIVE - Javier Díez-Domingo (DRIVE coordinator, FISABIO)
3. Setting the scene: EMA perspective on influenza vaccines - Marco Cavaleri (EMA)
4. Influenza VE studies in Europe. Current landscape and how did we get here - Pasi Penttinen (ECDC)
5. Governance in DRIVE - Laurence Pagnon (SP)
6. Lessons learnt from the pilot season 2017/18: Vaccine effectiveness results & study tools developed by DRIVE / Brand specificities / Study tools for improvement (Systematic review on bias & confounding; study support application; framework for data analysis; guidelines for interpreting IVE results) / Results presentation
7. DRIVE communication plan and debate: How to best communicate IVE results? - Hanna Nohynek & Riia Järvenpää (THL), Sharon McHale (SEQIRUS)
8. Innovative IVE study approaches: proposal and debate - Marga Riera & Anke Stuurman (P95)
9. Getting involved in DRIVE - Javier Díez-Domingo, Topi Turunen (FISABIO)

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?

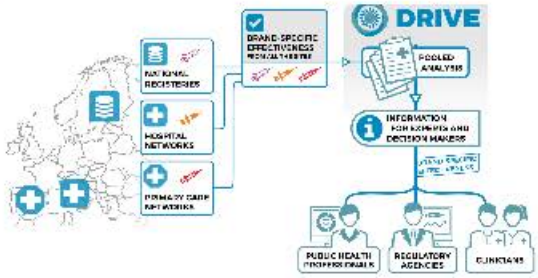
Regulatory authorities	Public Health Institutes	Researchers /scientists	Health care professionals	Patients & patient organizations	Media
Straight communication from the DRIVE project.	Answered at the "when" row.	Communication to scientists outside DRIVE through peer-reviewed publications (because that's 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.

Sep 2018 · 30 days

TWEET HIGHLIGHTS

Top Tweet earned 5,731 impressions

There is a need for robust Influenza Vaccine Effectiveness data. See how #DRIVEflu works to match the need: drive-eu.org/index.php/proj… #H2020 @IMI_JU @EFPIA @EU_H2020 pic.twitter.com/kKAd7H3oZ8



1 8 13

View Tweet activity

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Top Follower followed by 9,098 people

Melvin Sanicas MD

@Vaccinologist FOLLOWS YOU

Physician + Scientist • Gates Global Health Fellow • @TED_Ed Educator • #VaccinesWork #InfectiousDiseases #GlobalHealth

View profile

View followers dashboard

Top mention earned 65 engagements

Mónica VázquezMoreno

@MoniVazquezMor · Sep 16

Arrancamos reunión anual proyecto @drive_eu. @javierdiezd presenta el proyecto a nuevos socios y el gran reto de los estudios piloto para evaluar la efectividad de la vacuna de la gripe #influenza pic.twitter.com/l9oEVTCmsk

10 20

View Tweet

Top media Tweet earned 4,725 impressions

What is the status of Influenza Vaccine Effectives (IVE) studies in Europe? Follow the hashtag #DRIVEflu to hear more from experts and decisions makers, as the DRIVE Annual Forum will start at 14:00 CEST. drive-eu.org/index.php/2018… #H2020 #EUHealthResearch pic.twitter.com/1Xt7xG4mB5

1 8 15

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SEP 2018 SUMMARY

Tweets	Tweet impressions
18	37.9K
Profile visits	**Mentions**
313	25
New followers	
26	