D1.5 Report on study platform governance implementation and adaptation

777363-DRIVE

Development of Robust and Innovative Vaccines Effectiveness

WP1 Governance:

Lessons learnt from the first season implementation and adaptations for the next seasons

Lead contributor	Laurence Torcel-Pagnon (12 – Sanofi Pasteur)
	Laurence.pagnon@sanofi.com
Other contributors	Sam Nye (9 – CoMO)
	Topi Turunen (1 – FISABIO)
	Miriam Levi (4 – UNIFI)
	Hanna Nohynek (6 – THL)
	Joris Vandeputte (11 – IABS-EU)
	Mendel Haag (14 – SEQIRUS)
	Pieter Niels (11 – IABS-EU)
	Margarita Riera (4 – P95)

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V0.2	14 Feb 2019	Integration of first WP1 comments and updates
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V1.0	30 April 2019	Integration of SC comments and final version

[1] **Use one of the following codes:**
R: Document, report (excluding the periodic and final reports)
DEM: Demonstrator, pilot, prototype, plan designs
DEC: Websites, patents filing, press & media actions, videos, etc.
OTHER: Software, technical diagram, etc.

[2] **Please choose the appropriate reference and delete the rest:**
PU = Public, fully open, e.g. web;
CO = Confidential, restricted under conditions set out in Model Grant Agreement;
CI = Classified, information as referred to in Commission Decision 2001/844/EC.

Contents

1. Publishable Summary

This report provides an overview of the governance of the Influenza Vaccine Effectiveness (IVE) Study Platform to date and provides an insight into the adaptations made following feedback over the course of the first year of IVE studies. Key activities covered include:

1. Activities and adaptations (composition and work plan) of the Independent Scientific Committee (ISC) and Quality Control and Audit Committee (QCAC)
2. Review of WP7/vaccine manufacturers written interactions and process optimisation
3. Methods utilised to engage with external stakeholders (including study partners)
4. A review and changes made following feedback received throughout the first year and following the Annual Forum in September 2018.

Overall, this first pilot year has provided many opportunities for development, in particular, 1) increased communication around the study platform governance 2) increased role and improved definition of the involved ISC and QCAC committees and 3) process improvement, were highlighted as areas for optimisation. The Public Private Partnership (PPP) structure was identified as a key benefit for the participants in the Consortium but also conversely as an area creating new challenges when confronted with sentiments of PPP hesitancy, especially from the public domain stakeholders. To be overcome these hurdles, there is need to further communicate in transparent manner the governance structures and processes of DRIVE and strengthen the value of data from the IVE studies by enlarging the study platform with new research collaborators and/or innovative means to use open data.

2. Introduction

DRIVE has established **initial study platform governance** (see Figure 1) to perform the Influenza vaccine effectiveness (IVE) studies to support the vaccine performance monitoring by relevant stakeholders and answer to EMA regulatory guidelines by reporting brand-specific IVE at the end of the influenza season. Because this governance is unique and innovative in the European environment, it was planned to **evaluate its acceptability and performance throughout the 5 year project,** collecting feedback from both external stakeholders and DRIVE partners. By the end of the project, the established platform should provide the best suitable governance for a joint public private evaluation of brand-specific IVE in Europe.

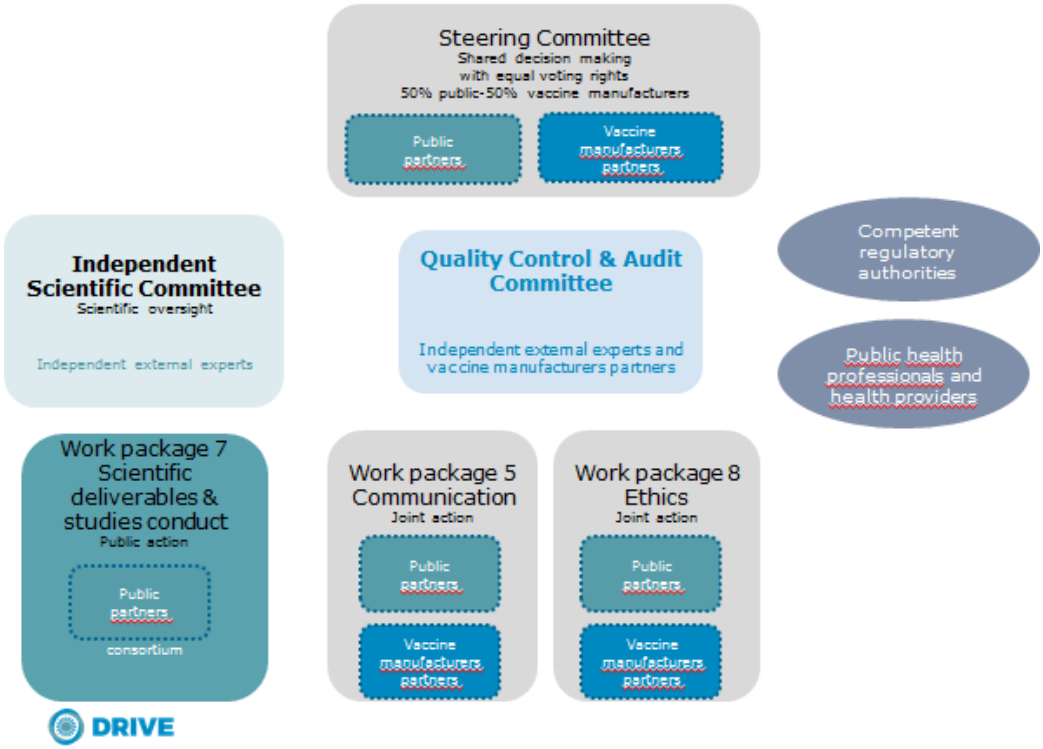

Figure1: Initial Study platform governance in DRIVE for the 2017/18 pilot season

See Annex1 for the description of the study platform governance.

This document provides a comprehensive overview of the initial study platform governance which was set up at the start of the project. It describes its implementation for the 2017/18 pilot season, explains how feedback has been sought from DRIVE partners and external stakeholders and describes how the platform is intended to be adapted for the subsequent influenza season(s). This document presents the first iteration and should be considered as an update of the original Governance SOP submitted in November 2017.

3. Construction of the study platform governance

Referring to the Governance SOP, this chapter presents how the study platform has been set up, including three main governance elements:

- Independent scientific committee (ISC)
- Quality control and audit committee (QCAC)
- The decision making flow and scientific deliverables review process
- Strategy for stakeholders engagement (including studies partners)

A. Independent Scientific Committee

In the interest of **independence of the scientific results, rigour and transparency**, it was agreed at the outset to establish an **Independent Scientific Committee** (ISC) to support the scientific leadership of the project.

In September 2017, a descriptive proposal was developed by the WP1 to explain roles/ responsibilities and composition foreseen for the ISC (see Annex 2). The selection of candidates was managed by the DRIVE Steering Committee (SC), which was composed of 6 members from the public partners and 6 from vaccine manufacturer partners, using a transparent and documented process.

- The SC generated a list of potential candidates based on the following predefined criteria:
    - Expertise in at least vaccine effectiveness surveillance (influenza specific) or statistics (specific to vaccine effectiveness analysis)
    - Other preferred expertise areas: Influenza strain surveillance and testing, vaccination programs, observational research, secondary database research, influenza clinical expertise
    - No recent affiliation with any of the consortium members' institutions (based on date of the call text April 2016)
    - Preferably EU experts (or experts with a good knowledge of EU environment) coming from various stakeholder groups (public health institutes, regulatory authorities, research institutes and organisations)
    - Expected additional representation of international organisations (WHO, CDC, ECDC)

  From the list of 33 pre-identified potential candidates, each SC member selected and ranked 10 experts based on his/her assessment against these criteria. The scores of the 12 SC members were compiled and discussed during a SC meeting. As it was foreseen that some of the potential candidates would decline, it was decided to work in an iterative process. Ten candidates were considered for the first wave of contact. The consortium's public coordinator, FISABIO, engaged in discussions with the proposed candidates. At the end, out of the eighteen experts contacted, five agreed to be part of the ISC.

  As of January 2018, the ISC is composed of 5 members:
    - **Dr. Hector Izurieta (FDA, US),**
    - **Prof. Elisabeth Miller (PHE, UK),**
    - **Dr. Mark Miller (NIH, US),**
    - **Dr. Stefania Salmaso (independent, IT)**
    - **Prof. Marianne van der Sande (Institute of Tropical Medicine, Antwerp, BE)**

  The experts' short resumes are available at the DRIVE website (https://www.drive-eu.org/index.php/governance/independent-scientific-committee/).

The ISC members signed an Advisory Agreement; contracts are established between FISABIO and either the expert's organisation or the expert directly. DRIVE proposes compensations for experts/organisations based on ECDC standards and rules: ISC members are not paid for their service but are reimbursed for DRIVE meetings and associated travel expenses.

Throughout the year, the ISC had several teleconferences and two face-to-face meetings. The secretariat of the ISC is provided by FISABIO and Synapse (under the Work Package 6 task 6.1.2).

The ISC's mandate is to evaluate and endorse the scientific deliverables of the DRIVE project developed by the public Work Package 7 (WP7) and to provide advice on their review process and communication components. Specifically, ISC roles and responsibilities are the following:

- Review WP7 scientific deliverables:
  - Protocols for type- and brand- specific influenza vaccine effectiveness (IVE)
  - Seasonal report of IVE studies conducted
  - Report on feasible novel and innovative approaches for measuring IVE
  - Report on virus characterisation and molecular epidemiology
- Provide comments to WP7
- Review written feedback from vaccine manufacturers and decide on integration of their comments or organize point by point response with WP7; Produce a document summarising the review
- Endorse the final scientific deliverables of WP7
- Advise the General Assembly on the independence and transparency of the scientific review
- Advise the WP1 about the study platform governance
- Advise the WP5 about key scientific communications and stakeholder groups

During the year 2018, the ISC reviewed the following WP7 deliverables:

- The two core protocols for type- and brand-specific IVES (field-based studies Test Negative Design TND and population database cohort studies)
- The Statistical Analysis Plans (SAP) for the pooled analysis
- The report on feasible novel and innovative approaches for measuring IVE
- The first seasonal pooled analysis report of conducted IVE studies

The details about the WP7 review process are described in the section C of this chapter.
A dedicated private folder on the DRIVE SharePoint was created for ISC reviews.

B. Quality Control and Audit Committee

As part of the study platform governance, it was agreed to set up a **Quality Control and Audit Committee** (QCAC) to advise the Steering Committee on the compliance and quality of the studies. The QCAC is designed to be a quality mechanism balancing the fully public and independent ISC group. It should be an added value of having industry part of the public-

private consortium with expertise in quality management, regulatory aspects, guidelines and standard operating procedures. The QCAC should **support vaccine manufacturers regulatory obligations on EMA guidelines, monitoring the quality of the data and the procedures**.

In January 2017, a descriptive proposal was developed by the WP1 to explain roles/ responsibilities and composition foreseen for this advisory committee (see Annex 2). The selection of candidates was managed by the DRIVE Steering Committee using a transparent and documented process.

- The Steering Committee was asked to generate a list of potential candidates based on the following predefined criteria:
    - Expertise in quality, standard operating procedures, compliance, medical governance, study auditing (e.g. qualifications in GCP GVP GEP) and financial auditing
    - For independent expert, no recent affiliation with any of the consortium member institutions (based on date of the IMI call text April 2016)
    - Preferably EU experts coming from various stakeholder groups (public health institutes, regulatory authorities, research institutes and organisations).
    - Qualified vaccine manufacturers' representatives will be proposed by each company.

  It was expected to have three independent external experts and four qualified vaccine manufacturers' representatives in this advisory committee. However, it was very difficult to identify independent external experts. The requested expertise can be mainly found in Contract Research Organisations (CROs) or auditors/consultants who are used to receiving compensations for the work performed. The same rules were proposed as for the ISC members (experts are not paid for their service but are reimbursed for DRIVE meetings and associated travel expenses). Finally, only one independent expert agreed to be part of the QCAC.

  Sanofi Pasteur, GSK and Seqirus proposed one expert with the appropriate expertise & experience from their companies. It is worth noting that within the companies' organizational structure, quality departments are separate from the functions who are concerned with the study conduct and results, and ensure the quality of their data. Their need follows point 44 of the REGULATION (EU) No 536/2014 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC.

  The QCAC was composed of 4 members:
    - **Jaime Ballester – independent external expert (CRO Experior)**
    - **Nathalie Lavis, Sanofi Pasteur expert**
    - **Anne-Marie Kirby, GSK expert**
    - **Coree Forman, Seqirus expert**

The QCAC became active in May 2018, commencing with an induction meeting with QCAC members and the Coordination team.
During the year, the QCAC had several teleconferences and one face-to-face meeting.

The QCAC's mandate was to:

- Establish a detailed work plan following the project tasks and needs, including a defined audit procedure and list of audits to be conducted, as well as a quality control procedure and/or checklist for review of documents and processes. The procedures should follow the appropriate international standard guidelines.
- Audit the study platform governance in accordance with the procedure defined upfront:
    - Verify adequacy and transparency of funding sources and funding allocation;
    - Verify adequacy and transparency of the review processes and appropriate documentation for WP1-6/8 and for WP7 deliverables
    - Verify adequate declaration of potential conflicts of interest; evaluating potential conflicts of interest
- Ensure that adequate quality control is performed on sites and supervise auditing for the WP7 studies (e.g. onsite visits for protocol implementation per season); advise WP3 on the development of the two deliverables: D3.4 Report on the comparison of adapted local protocols and Ethical Committee evaluation in each study site, D3.5 Report on quality and feasibility evaluation. A CRO may be selected to provide operational support for the conducting of on-site audits under the oversight of the QCAC.
- Report findings to the Steering Committee and provide advice, recommendations and proposed action plans, when needed. It will be used to update relevant deliverables (e.g. deliverable D1.2 Governance SOP).

In September 2018, the QCAC delivered its work plan to the SC. It was expected that the QCAC will interact on quality of data and processes for the subsequent season (2018-19). The QCAC works was managed through the DRIVE SharePoint.

C. Decision-making flow and scientific deliverables review process

The core principle is to ensure a full traceability of the vaccine manufacturers' inputs on the scientific deliverables**.**

Brainstorming sessions between WP7/Vaccine manufacturer partners

As planned, the **first brainstorming session was organized on October 2nd 2017** in Paris, hosted by IRD between WP7 and vaccine manufacturer partners. The objectives of this brainstorming session were to establish the principle and generic characteristics of the scientific deliverables to ensure that these would meet the EMA requirements before their development was initiated by WP7. . It was organized 3 months before the development of the first WP7 deliverables.

The first objective of the meeting for the pilot season 2017/18-was to identify what should be updated in existing ECDC generic and country adapted protocols for the preparation of the core protocols to be used in DRIVE (deliverables D7.1 and D7.2).

- Vaccine manufacturer partners prepared a list of their key requirements upfront based on the analysis of the adequacy of the current ECDC generic protocols in terms of meeting EMA influenza vaccine guidelines.
- WP7 partners shared adapted country-specific ECDC protocols, highlighting required changes for the 2017-18 season.

The second objective was to define the outline (i.e. template) for the Statistical Analysis Plan (SAP) and the pooled analysis report, and the third objective was to start discussing what could be the innovative approach/ methodology for the preparation of the report on the feasibility model and innovative approaches (Deliverable 7.3)

The **second brainstorming session was organised on November 27th 2018** in Brussels between WP7 and vaccine manufacturer partners under the premises of the Sachsen Anhalt regional office. The objectives were to discuss:

- The updated principles for the statistical analysis plan for 2018-19 based on the lessons learnt from the 2017-18 season,
- How open data can be a strategy proposed by DRIVE to increase the study platform's ability to do meta-analysis of Vaccines Effectiveness studies conducted by external stakeholders,
- Priority-setting of studies
- Study governance and WP7 deliverable review process update based on the lessons learnt from the 2017-2018 season
- Study documents (WP7) review process

WP7 scientific deliverables review process:

In 2018, the WP7 documents were each written with one public institution as the lead:

- ISS in the case of the test-negative design (TND) core protocol for type and brand specific IVE studies (also referred to as field-based studies) – in January/February,
- THL in the case of the cohort core protocol for type and brand specific IVE studies (also referred to as population database studies) – in January/February,
- P95 in the case of the report on feasible novel and innovative approaches for measuring IVE, the SAP (site specific and pooled analysis) and the first seasonal pooled analysis report of conducted IVE studies –respectively in June/July and in August/September.

For each document the same process was applied: authors from the leading institution prepared a draft which was first circulated within WP7 by email. After comments from the other WP7 partners, the document was sent by Synapse to the vaccine manufacturers and by FISABIO to the ISC who reviewed the document as outlined in the scheme below (Figure 2).

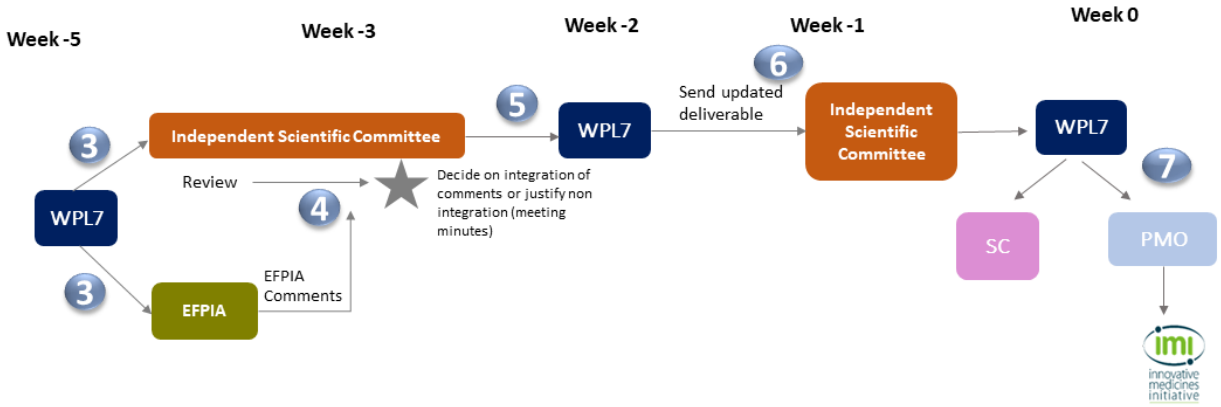

Figure 2: WP7 and ISC review process for the WP7 scientific deliverables

ISC members reviewed the document and provided comments; FISABIO and SYNAPSE facilitated the compilation of ISC comments as needed.

Each vaccine manufacturer reviewed the document in parallel and provided written comments to FISABIO/SYNAPSE who made the compilation before sending to the ISC. Vaccine manufacturers' comments were tracked in an excel file where ISC made point-by-point responses and decided whether to integrate them or not; ISC addressed its recommendations to WP7, updated the document accordingly and returned it to the ISC; WP7 integrated ISC comments, or, alternatively, organized point-by-point responses; if needed another review was organised; ISC endorsed the final version of the deliverables.

For the most part, the designated timelines of WP7 deliverables review were respected by vaccine manufacturers and the ISC alike. However, delays resulted in several occasions either from the document not being available by the predefined deadline, or from the unexpected extent of reviewers' comments which in majority necessitated two rounds of review (in case of the core protocols, SAPs and the pilot season study report). For the pilot study report, ISC decided to anonymize brands because of the data quality and sample size limitations.

D. Strategy for research stakeholders' engagement

Sites selection and tender process

It was originally foreseen that new institutions could join the DRIVE consortium in one of two different ways:

1. European Union and EEA public health institutes and other public organizations already working on influenza vaccine impact evaluation could join the project as *Associate Partners* through a contractual arrangement with FISABIO, DRIVE's Coordinator.

2. Other research organizations would be eligible to participate through an annual Call for Tenders. The institutions whose proposals would be awarded by DRIVE would join the project as *Research Collaborators*.

Collaboration would include sharing of data as well as contributions to methodological and scientific discussions and participation in project meetings, with the DRIVE consortium providing technical and financial support.

In the first pilot season 2017/18 of the project, 2 institutions joined the project as Associate Partners:

- **National Influenza Center of Austria, located at the Medical University of Vienna**
- **Regional Public Health institute of La Rioja, Spain.**

The first **call for tender was launched on May 2nd 2018** for the flu season 2018-19. The call included a tender specifications document, an application form and provided the links to the DRIVE core protocols for TND and database cohort studies. It was open for any organization, institution or network with interest and capacity to perform influenza vaccine effectiveness studies in Europe. To fulfil the admissibility requirements, the applicants filled in an application template with their basic information and their previous work in the field. They also provided a technical and financial proposal to describe the work to be done, possibly supplemented by other relevant documents such as a study protocol.
The original deadline to submit the proposals was on 10th June 2018 but was extended to **25th June, yielding 12 proposals.**

Proposals were reviewed by the Steering Committee (SC) of DRIVE. Each SC member institution scored the proposals using predefined criteria:

- Relevant expertise and experience of the applicant (0–10 points)
- Proposed research collaboration for DRIVE (0–30 points)
- Cost effectiveness and level of possible co funding from the applicant (0–10 points)
- Supplementary points (bonus) for innovative approach (0–20 points)

As a number of proposals originated from some Steering Committee member institutions' home countries, it was agreed that these institutions would not score those proposals. This was balanced in scoring by looking at average, rather than total, scores. Upon receiving the proposals, FISABIO asked several sites for additional information and clarifications. Cost-effectiveness was a notable selection criterion. The budget of certain proposals was renegotiated.

At the end, **8 proposals were selected by consensus by the DRIVE SC** and a Research Collaborators agreement was signed between FISABIO and the following institutions:

- **National institute for infectious Diseases (Matei Bals) Romania**
- **Helsinki University Central Hospital, Finland**
- **Kapodistrian University of Athens Medical school, Greece**
- **Bambino Gesu children's hospital & affiliated network, Italy**

- **CIRI-IT, Italy (2 proposals)**
- **Vall d'Hebron University Hospital, Spain**
- **University of Surrey (novel proposal by an existing DRIVE partner)**

Further details about the first call for tender are described in the deliverable D2.1 Annual tender for IVE study conduct submitted to IMI in October 2018.

E. Stakeholders interactions and governance communication

EMA interactions and regulatory pathway

The DRIVE project was set up to generate brand specific IVE in order to fulfil the requirements described in the European Medicines Agency (EMA) guideline on influenza vaccines. Addressing this new requirement through a public private partnership, by liaising with public health partners who have an existing infrastructure in place, is considered key to enhance the EU/EEA capacity to collect brand specific IVE and to overall increase our understanding of vaccine performance. The public private partnership collaboration, brings specific considerations for communication or submission of vaccine effectiveness data with the EU regulatory authorities. In addition, and separate from the procedural obligations of the Marketing Authorisation Holders (MAHs) related to their products' 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.

For these reasons, parallel engagements were initiated with EMA, each with a specific aim.

- Firstly, on behalf of the whole Consortium (via DRIVE's Work Package 5) led by IABS-EU for the broader scientific engagement not pertaining directly to the obligations of the manufacturers.
- Secondly, on behalf of the Influenza Vaccine MAHs relating to the specific obligations of the MAH and regulatory procedural pathways for submission for product specific vaccine effectiveness. A letter was sent by Vaccines Europe to EMA in Sept 2018 to present Vaccines Europe's comments on CMDh/CHMP feedback on regulatory procedure for annual IVE procedural aspects and data assessment. It is important to note that one of the vaccine manufacturers (MedImmune) is not part of the DRIVE consortium and needs to interact through Vaccine Europe.

At the core of both engagements is the need to maintain alignment between the different regulatory bodies and relevant committees in relation to the vaccine effectiveness requirement (for further details, please refer to the deliverable *D4.7 Evaluation reports of how the vaccine effectiveness results could fulfil the new regulatory requirements* submitted to IMI in Sep 2018).

To coordinate these regulatory interactions, the Consortium established a working group on Regulatory Affairs, led by IABS-EU, including work package leads and co-leads, as well as additional regulatory experts. The **regulatory group** was set up in such a way that multi-stakeholder dialogue is promoted. The group first met by TC on **June 29 2018**.
Members are Hanna Nohynek, Javier Diez Domingo, Mendel Haag, Laurence Pagnon, Gael Dos Santos, Margarita Riera, Joris Vandeputte, Topi Turunen, Monica Pagni, Pieter Neels (Chair), Sharon McHale, Cédric Mahé, Ed Geuns, Romain Hahn, Géraldine Solin, Bram Palache, Jos Nauta, Michel Stoffel, Kelly Hoffner, Philippe Rocolle.

The Annual Forum meeting in Rome, September 2018, was the first opportunity to present the DRIVE regulatory group and its working process in the presence of **Marco Cavalieri from EMA, identified as the central coordinating contact** to facilitate the regulatory interactions from the Consortium level and maintaining an aligned approach.

Subsequently, the **DRIVE Consortium had a virtual meeting with the EMA Vaccines Working Party (VWP) on December 5th 2018**. The objective was to present the DRIVE project, the results of the first year pilot 2017-18 season and the 2018-19 plans. The pooled analysis report from the 2017-18 pilot season was sent to EMA as pre reads of that meeting.

Marco Cavalieri and VWP members acknowledged that the influenza season 2017/18 was considered a pilot season. They also noted that the data presented were based on a limited number of sites using partially differing study protocols. Therefore, several limitations were identified, including limited sample size and heterogeneity between sites. However the overall project and the pilot year study report were considered encouraging.
The DRIVE consortium has been asked to continue liaising with the VWP for discussion on methodology as needed.

As a consequence, Marco Cavalieri answered the MAH's letter about regulatory procedure through Vaccines Europe on December 12th 2018. He explained that because the results are insufficient to allow a meaningful discussion with regulators (in light of the limitations identified), it would be premature this year to request submission of formal variations for assessment by competent authorities. The CMDh agreed to wave this requirement for the 2017-18 season.

Stakeholders' interactions on the research agenda and study platform governance

In the first year of the project, DRIVE developed a research agenda to identify potential areas in relation to IVE where increased knowledge could support decision making for regulatory purposes and for public health programs. The research agenda was available on the DRIVE website for public consultation from May to Mid-July 2018. Despite alerting to this opportunity via social media channels and active invitations to provide comments to relevant key actors in the field, DRIVE was not successful in soliciting inputs from external stakeholders and identifying possible new areas for investigation.

During the first DRIVE Annual Forum that took place in September 17th 2018 in Rome, half-a-day was reserved to a **WP1 workshop targeting external stakeholders**, open to DRIVE Consortium members. The aim of the workshop was to discuss the research agenda and study platform governance to collect insights from external stakeholders. It was hoped this would identify top priority research questions for DRIVE actions and synergies with other researchers/networks to be validated by the DRIVE Steering Committee and to be used to fill in the gap analysis for the 2019-20 call for tender. It was also expected to be an opportunity to explain the study governance model, assess external stakeholders' levels of understanding of such a model and to identify external stakeholders' barriers to the concept, and to extract suggestions of potential adaptations to be incorporated into the evaluation framework for governance adaptation for the 2018-19 influenza season. The outcomes of this workshop are described below.

A **web-based governance survey was conducted from 25 September to 8 October 2018**, right after the Annual Forum, with the aim to evaluate the initial study platform governance proposed to conduct the pilot studies during the 2017-18 flu season. 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) - were invited to participate. The surveys generated 34 responses with varying completion rates in each group. The highest response rate (65%) was reached among external stakeholders, followed by advisory committee members (50%, in each ISC and QCAC) and then by DRIVE partners (42%). 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 survey highlighted the need to further develop the roles of the advisory committees (QCAC, ISC) and to adapt the study platform governance and communication for timeliness and efficient interactions within the consortium. In particular, there were several requests from consortium members for more regular email communication in the form of newsletters. The key messages from the governance survey which were used to update the study platform governance are detailed in the next Chapter. Further details about the Governance survey are given below and are also available in the deliverable *D5.5 Report on the collected feedback from Layer 1 Stakeholders* submitted to IMI in December 2018.

A **webinar targeting all with an interest in influenza vaccine studies was organized on November 16th, 2018**,, with the aim to disseminate the project status and governance and the main results of the first Annual Forum to external stakeholders. The webinar was attended by 15 external stakeholders coming from various organisations in Europe (Netherlands, Croatia, Norway, Ireland, Greece, Spain, Hungary, Estonia, Luxembourg, France, UK).

4. Study platform governance evaluation and key performance indicators

A. Analytic framework

To evaluate the study platform governance, 6 thematic areas have been chosen as relevant for the governance evaluation [1] and further developed in 18 criteria for the DRIVE study platform governance evaluation (Figure 3). An analytic framework has been built around those criteria defining the questions of interest, the key performance indicators (KPIs) and their assessment methods (Annex 4).

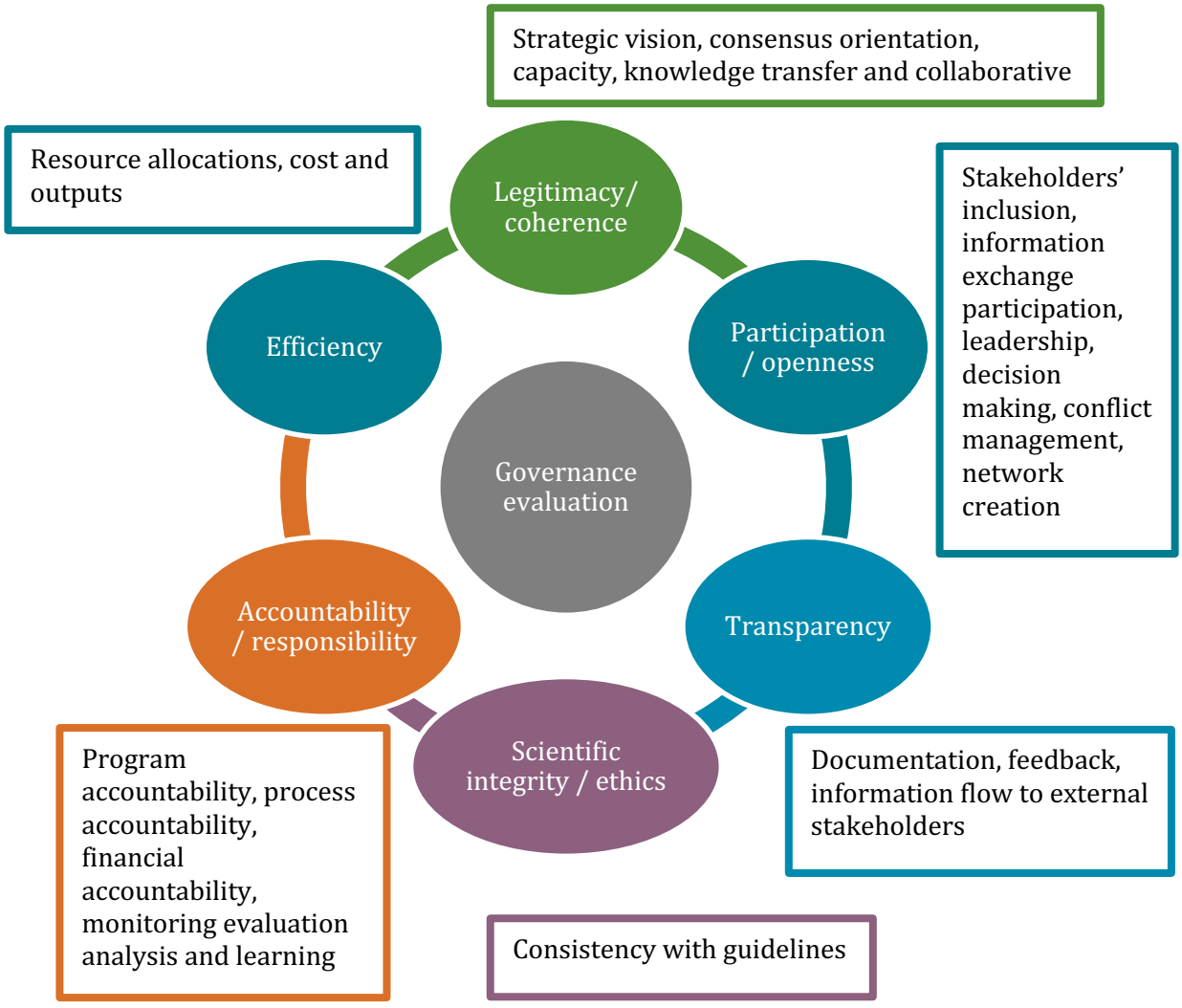

Figure 3: Study governance evaluation criteria

[1] *Sameen Siddiqi and all. Framework for assessing governance of the health system in developing countries: Gateway to good governance – Elsevier 2008. doi:10.1016/j.healthpol.2008.08.005*

B. First year evaluation

The first year evaluation was conducted though different ways: workshop, surveys and meetings as detailed below. Most of the key performances indicators were assessed and baseline values established, building on the key aims agreed in year 1. A full breakdown of the KPIs and targets for next year are provided in Annex 4.

WP1 Workshop:

During discussions with external public stakeholders, it was agreed that sharing data/Open data is becoming a key component for transparency that may facilitate DRIVE synergies with other initiatives / networks; some public institutes explained that they cannot share their data twice for the same research question; other public organisations may also not necessarily be willing to become a DRIVE partner for this reason.

➔ *Open data in DRIVE was discussed as a potential option which should be further investigated to increase the potential of the study platform for IVE; it is in full compliance with European Commission laws and IMI spirit*

Study governance survey:

The response rate was quite good among external stakeholders (65%) but less so in DRIVE partners and advisory committees (respectively 42%, 50% and 50%)

➔ *It is key to get feedback from partners and all members of the advisory committees (due to their limited numbers) – launching the survey after the Annual meeting is not optimal ; it should be managed differently for the next evaluation to increase the response rate (it could be managed during the Annual meeting)*

It was generally agreed that annual brand-specific vaccine effectiveness (IVE) estimates are important and that PPP is the best or one possible good option. A few divergent views emerged externally regarding the project's study governance, with requests for vaccine manufacturer partners to be removed from the sites selection and study review. There were a number of requests for further engagement with patient organisations, civil societies (CSOs) and health care professional groups to boost trust in the PPP and more widely, to reach a broader audience. Another common suggestion was to raise awareness of the levels of scrutiny applied to vaccine manufacturers.

➔ *Work with WP5 on study governance communication and look at which patient groups, HCP groups and CSOs might be interested in collaborating with DRIVE.*

The overall explanation on the study governance was deemed good for external stakeholders and DRIVE partners but there were some valuable suggestions for further improvements:

➔ *Use feedback to improve governance communication and update the Q&A on the website "who is who" ; what is the exact role of vaccine manufacturers", "do manufacturers have a veto capacity regarding new partners".*

More than half of the external stakeholders and one ISC member found it somewhat or completely appropriate that the sites selection was made by the SC composed of 50% public and 50% vaccine manufacturer members, compared to 82% among DRIVE partners. However for the other 4 external stakeholder respondents and one ISC member divergent views emerged. Proposals were made to engage ISC in the sites selection. This point was also raised during the WP1 workshop discussions in September 2018.

➔ *Sites selection process should be revised involving ISC for scientific relevance and independent review*

The 2 ISC members who responded to the survey questioned the work flow and process for the WP7 deliverables review: they felt that the way it currently works is either inefficient or quite efficient, with difficulties in making comments on vaccine manufacturers documents and clearer guidance being required. The fact that they felt that they do not receive enough information on what was taking place within DRIVE was mentioned several times.

➔ *The WP7 deliverables review process should be adjusted to integrate ISC comments and be more efficient. Communication with ISC members should also be improved.*

Most of the external stakeholders and the DRIVE partners 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, agreed that the advisory committees have the required expertise and experience. Most DRIVE partners found the role of the QCAC completely or somewhat appropriate, whereas divergent opinions emerged from external stakeholders

➔ *Role of the QCAC should be clarified and better explained*

Consultations for study governance adaptation before implementation

All external and internal feedback was reviewed within WP1. The WP1 and SC members worked and discussed about proposals for study governance adaptations during a face to face meeting on November 27th 2018. During this meeting the discussions were focused on defining the requested adjustments for the ISC, the QCAC, the sites selection through the tender process and the study documents review processes.

The updates proposed for the QCAC were discussed during a virtual meeting on December 3rd 2018 with QCAC members and the CT and comments were incorporated into the below proposals for implementation.

The updates proposed for the ISC were discussed during a virtual meeting on January 10th 2019 during a joint ISC/SC meeting. Feedback from ISC members was collected and incorporated into the below proposals for implementation.

5. Proposals to adapt the study platform governance

A. Independent Scientific Committee

In agreement with the ISC, the following changes are proposed for the 2018-19 flu season to be effective in Q1 2019.

Enlarge role and mission of the ISC:

The mandate of the **ISC is enlarged with its scientific evaluation and recommendations in the sites selection process through the yearly tender.**

The sites selection will be organised in a 2 step approach coordinated by FISABIO/SYNAPSE:

- The ISC will perform the scientific evaluation of the sites proposals ; it will consist of a quantitative evaluation, scoring and ranking of the proposals based on 5 pre-defined criteria:
  - Ability to adhere to DRIVE generic protocols (TND and cohort protocols) or level of appropriateness for DRIVE for innovative studies (15 points)
  - Ability to capture brand-specific information (10 points)
  - Estimated sample size (10 points)
  - Scientific reliability of the laboratory testing or ability to send samples for DRIVE testing (10 points)
  - Expertise in conducting IVE studies (5 points)

  The ISC will provide their scientific evaluation (one score per site with a ranking of the proposals) and general recommendations to the SC along with the list of questions/clarifications to be addressed to the sites if any.

- The SC will perform the strategic selection of the sites and will decide the allocated budget. It will consist of a qualitative assessment based on 4 pre-defined criteria:
  - ISC scientific evaluation and recommendation (ISC scoring, number of points /50 and ranking of the proposals)
  - Ability to fill gaps and relevance for pooled analysis in DRIVE, specifically coverage of the different brands (3 levels: high, medium, low)
  - New partner (3 levels: high, medium, low)
  - Cost effectiveness / Co funding / sustainability (3 levels: high, medium, low)

- The proposed timelines for 2019 are:
  - February: launch of the call for tender
  - Mid-April: deadline for sites applications
  - May: ISC scientific evaluation and SC strategic pre selection / budget allocation
  - June: deadlines for sites answer to ISC/SC questions
  - Mid-June: SC final decision
  - Mid July: invitations of the new sites to the Annual forum

Additional members in the ISC:

Additional members will be sought in 2019 to decrease the workload, add specific expertise and increase institutional representation. Several suggestions are made:

- Experts from ECDC and US CDC, SAGE group or Fogarty International Center
- Experts in statistics, virology, ethics…

The list of potential additional candidates will be jointly developed by the ISC and the SC. ECDC will be contacted by the SC to discuss about their potential participation in this independent advisory committee.

B. WP7 scientific deliverables review

The review process of WP7 scientific deliverables envisaged initially in which the ISC and the vaccine manufacturers reviewed the deliverable in parallel was considered to generate a lot of redundant comments. **In order to streamline the review it is proposed to send the deliverable first to the ISC for a first round of review, followed by integration of their comments in the deliverable, after which vaccine manufacturers would provide consolidated comments**. These comments would be evaluated by the ISC, after which WP7 would produce the next revised draft to be endorsed by the ISC. If considered necessary, an additional round of review could be performed (see Figure 3 below)

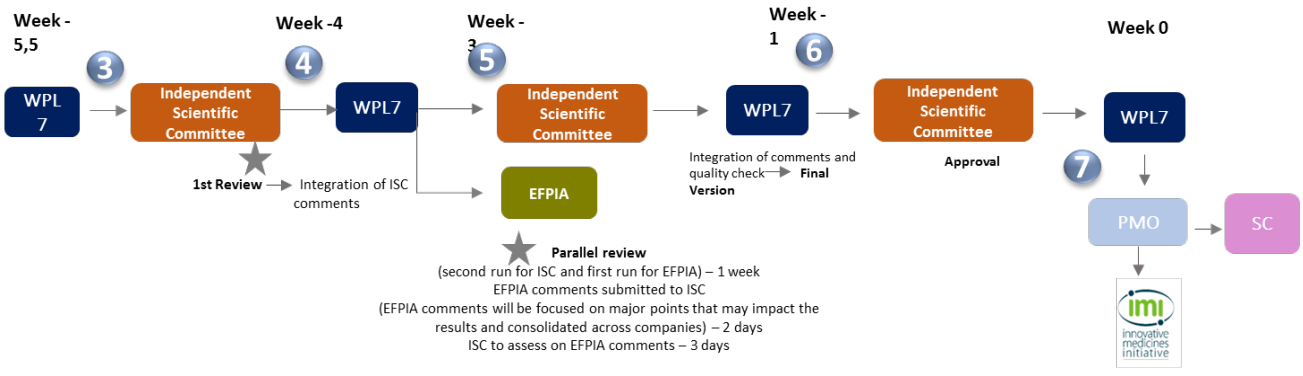

Figure 3: updated WP7 scientific deliverable review process

C. Quality control and audit committee

Updates in QCAC membership:

In November 2018, the membership of the QCAC was changed for several reasons: organisation change within 2 companies and resignation of the independent external expert (due to high workload with no economic return).

The QCAC is now composed of 3 members being Clinical Quality Assurance experts and representatives of 3 vaccine manufacturer partners:

- **Ann-Marie Kirby (GSK)**
- **Claire Pope (Seqirus)**
- **Sophie Gilles (Sanofi Pasteur)**

A third party auditor will be selected as an independent external expert for the conduct of sites audit when needed.

Adjusted and focused role and mission:

The mission of the QCAC is refocussed on the evaluation of the quality of the study conduct, the data collection and the pooled analysis performed to provide the brand-specific influenza vaccine effectiveness report.

The QCAC will ensure data integrity to the Independent Scientific Committee, to the Steering Committee and ultimately to EMA.

QCAC will assess the following items:

- Quality of the study conduct: the study was conducted in compliance with regulatory standards, the site protocol and the local SOPs based on the information collected in the “DRIVE site visit checklists” completed by the sites during influenza season (from October to April). QCAC evaluation in April

- Quality of the data: the data management report (DMR) and the quality check report produced by P95 show that the data collected from the sites were processed in compliance with P95 data management plan. Availability of DMR by mid-May for QCAC evaluation

- Quality of the analysis: the pooled statistical analysis report produced by P95 matches with the Statistical Analysis Plan (SAP). Availability of first draft version of pooled statistical report early June for QCAC evaluation

QCAC will develop 3 “Quality Criteria checklists” agreed with WP3 and P95. QCAC will record on these checklists the quality issues identified and an overall assessment which will be shared with the SC:

- To evaluate the quality of the study conduct at each site, QCAC will complete a “Quality Criteria checklist” for each site based on the “site visit checklist” information. For each site, QCAC will be able to make an overall assessment of the study conduct.

- To evaluate the quality of the data, QCAC will complete a “Quality Criteria checklist” based on data management report from P95. QCAC will develop the “Quality Criteria check list” for data quality evaluation in agreement with P95

- To evaluate the quality of the analysis, QCAC will complete a “Quality Criteria checklist” based on the pooled statistical analysis report produced by 95 and compared with statistical analysis plan

QCAC overall assessments for each step will provide recommendations to secure compliance which will be submitted to SC for approval. The QCAC recommendations should be:

a. No corrective action proposed
b. Unclear information provided and QCAC request for additional information to finalize evaluation (eg. site specific protocol to compare with DRIVE core protocol standards,…)
c. Corrective and/or preventive actions proposed
d. External and independent audit to be conducted at a specific site or on a specific process (extreme decision).

The conclusion of QCAC will be described in a quality report attached to the final report (ISC review – EMA submission): QCAC will describe how the quality of the data were assessed for the current Flu season and will suggest recommendations for improvement for the next season. The draft QCAC quality report will be submitted to the ISC and the SC for approval in June/July before submission to EMA with the annual report in July/September.

D. Open data for the study platform

Based on the lessons learnt from the first year, it should be acknowledged that the DRIVE IMI project is facing difficulties to on-board new Public Health Institutions (PHIs) in the project and increase its study platform to generate brand specific IVE estimates. One of

the barriers identified though several contacts made with PHIs is their reluctance to enter into a Public Private Partnership (PPP) as a formal partner.

For this reason, the DRIVE Steering Committee decided to approach the problem from a different angle. DRIVE ultimately does not need to access raw/individual level data. The DRIVE platform is mainly established to do a meta-analysis of Vaccines Effectiveness studies conducted by external stakeholders, trying to ensure brand IVE data is made available. Summary data access can be sufficient provided it allows performing the meta-analysis according to the pre-established statistical analysis plan. Secondary access to these data could be provided through an open data portal without any contractual link. This strategy can be leveraged through the current European Commission context of promoting open data and data sharing of public or European Union (EU) funded projects for the benefit of public health.

The portal will have to ensure that access is granted to institutions after registration and submission of a specific protocol. Specific Intellectual Property rights-related matters will need to be clarified for the user through a formal charter (use of the results, acknowledgment of the platform in publication, data transfer to external partners, duration of conservation, etc.). The best space to locate this data repository could be within the ECDC's remit, building on the TESSy tool.

To promote this open access strategy, the DRIVE project will need to set an example with the data from the 2018-2019 season and should investigate the possibility of making them available in Q3 2019. This data sharing should be widely communicated to encourage reciprocity.

As recommended by the IMI lawyer, since this type of data sharing is not included in the current Grant Agreement, the acceptability of the approach by the whole Consortium would need to be endorsed through an amendment to the Grant Agreement specifying this open access option.

Each participating site will be able to voluntarily decide to share its data on the platform under the terms and conditions of the platform Charter. The agreement of each site could be formalized through an electronic signature upon first accessing the platform, after Charter review or through a separate membership form, the acceptance form needs to be agreed later on, depending also on the hosting entity.

More generally, the DRIVE project should communicate on the benefit of open data for EU citizen public health and synergies between connected projects funded by the European Commission. Patient organizations and civil society could be an interesting communication avenue for this initiative. The DRIVE project would also investigate access to datasets through existing legislation (e.g. Spanish open data policy).

As next steps, DRIVE will have to define:

- A chart for data access (e.g. identification of institution/person, good practices and statement for publication reference)
- A minimal core data model needed to allow for brand specific VE meta-analysis and evaluate with ECDC the possibility for them to host the open data platform (Q1-Q2 2019).

E. Governance communication

Original content from the consortium should be uploaded to the website on a regular basis, to keep external stakeholders informed on the development and enhancement of the DRIVE governance model. This could be achieved through the publishing of blogs and news articles. Articles could simply describe improvements to the model and how these are made in response to challenges as they arise. If regular content is added about the governance aspect of the project, it should clearly demonstrate its importance and hopefully generate more interest.

6. Next steps and conclusion

The implementation of the study platform governance went well during the pilot flu season however, as expected, some adjustments should be made to improve its relevance and efficiency. In general, there was a request for increased levels of open communication within the Consortium and externally. The roles of the ISC and QCAC were identified as areas for optimisation and most respondents to the governance evaluation survey identified learning from public or private partners as a key benefit of the project. An outcome was for other external stakeholders to in fact identify PPP as a potential problem due to concerns about industry involvement. A potential solution involving the use of a platform for open data was identified and is now being explored to retain the benefits of the PPP but with optimal and sustainable engagement from a diverse range of external stakeholders.

As a summary, the implementation of the study platform governance adaptations are planned as described below:

Governance adaptations implementation	2019 Dates	Comment
Sites selection tender process with ISC & SC	Feb-Jun	Tender for flu season 2019-20
Identifying and selecting potential additional candidates for ISC	Feb-May	Jointly ISC/SC
WP7 scientific deliverables review process	Feb-Jul	Lead by WP7
QCAC quality criteria check lists development	Feb-May	Jointly with WP3 P95
Open data discussions	Mar-dec	Discussions with ECDC
Governance communication	Mar - Jul	Jointly with WP5

It is expected to collect feedback from external stakeholders and DRIVE partners by the end of the 2018-19 flu season (July-Sep 2019) to see how things were improved compared to the first season and discuss if there is room for further adjustments.

Since response rates to the WP1 and WP5 surveys in September 2018 were disappointingly low, especially among DRIVE partners, there is a proposal to increase this by administering them during, rather than after, the Annual Forum, by ensuring some dedicated time between sessions for participants to fill in the questionnaires. Delegates should be made aware of this in advance of the Annual Forum in the newly introduced internal newsletter and it should be clearly indicated on the agenda. There will also be an opportunity for people to discuss any concerns or suggestions at the Annual Forum should they wish to do so and this will also be made clear via the newsletter ahead of time. There should be reminders sent out to all following the Annual Forum, for those unable to attend and in case anyone fails to complete their survey while in attendance.

7. Annexes

Annex 1: description of the Study platform governance (seasons 2017-18 and 2018-19)

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 platform governance season 2017-18	Study platform governance season 2018-19
Study design **is carried out by public partners in Work Package 7 (WP7).**	No change
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 publish their own results.**	No change
New collaborators **are selected by the Steering Committee on a yearly basis through a public call with pre-defined criteria.**	New research collaborators/sites are invited to join DRIVE on a yearly basis through a public call. Their selection is organised in a **2 step approach: the Independent Scientific Committee performs the scientific evaluation** of the new research collaborators/sites proposals and provides its recommendations to the **Steering Committee who performs then the strategic selection** and decides the allocated budget. DRIVE is developing a chart and core data model to promote **open access strategy** and increase its study platform.
Pan-European pooled analyses **are performed by statisticians and data analysts at P95, a small-medium sized enterprise.**	No change

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.**	No change but in order to streamline the process the scientific deliverables are reviewed by the ISC (for a first round), followed by integration of their comments in the deliverable, after which vaccine manufacturers would provide consolidated comments to the ISC.
The Quality Control and Audit Committee **advises on compliance and quality of the studies.**	The Quality Control and Audit Committee assess the quality of the study conduct, the data collection and the pooled analysis. The conclusion of QCAC will be described in a **quality report attached to pooled analysis report** (ISC review – EMA submission): QCAC will describe how the quality of the data were assessed for the current Flu season and will suggest recommendations for improvement for the next season.
Data quality control and audits **are performed, if required, by a third party on behalf of the vaccine manufacturers to meet their regulatory requirements.**	No change
Ethics requirements **for the study platform are set by public and private partners in Work Package 8 (WP8).**	No change
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.**	No change
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.**	No change

Annex 2: ISC descriptive proposal for season 2017-18

Annex 3: QCAC descriptive proposal for season 2017-18

Annex 4: Governance analytical framework and KPIs for this year

Table 1: Key performance indicators of the study platform governance after the first year

Thematic area	Topic	KPIs	Measure & Target for next yr	Baseline (this yr)	Recommendations
Legitimacy / Coherence	**Strategic vision**	Ensure common vision: **understanding of importance to provide yearly brand-specific IVE** Convey that **PPP is an appropriate model** within which to deliver this project	% survey respondents Externally & Partners: 100% % survey respondents Externally: 75% Partners: 100%	Externally: very important/somewhat important: **100%** Partners: **94%** Externally: PPP is good or best option**: 70%** Partners: **100%**	Work with WP5 to engage in more external communications about the benefits of PPP and present how it works in DRIVE practices for the IVE studies (video) . Investigate if more CSOs could be involved.
	Consensus orientation	Stakeholders consider the **role of the ISC** appropriate Stakeholders consider the **role of the QCAC** appropriate	% survey respondents Externally: 75% Partners: 100% % survey respondents Externally: 70% Partners: 90%	Externally: roles are appropriate: **66%** Partners: **80%** Externally: somewhat or completely appropriate: **56%** Partners: **71%**	The reason for the lower % was not understanding the role so we must work with WP5 to ensure it is better communicated, e.g. on the website, video interviews of some ISC members. The QCAC has developed a detailed work plan of their activities which will be shared at the coming Annual Forum. A QCAC report will be appendix to the pooled analysis annual

		Support gained for a PPP approach to **site selection** (50% public and 50% EFPIA on the Steering Committee for decision making)	% survey respondents Externally: 75% Partners: 100%	Externally: somewhat and completely appropriate: **56%** Partners: **82%**	report submitted to EMA. Consider involvement of the ISC in the selection for scientific relevance and independent review. Explain the updated site selection process in the coming call for tenders.
	Capacity	**ISC** has the necessary levels of **expertise**	% survey respondents Externally: 100% Partners: 100%	Externally: agreed mostly or completely: **89%** Partners: **100%**	Consider adding members for institutional representation (e.g. ECDC, CSO) or specific expertise (e.g. virology, ethics)
		QCAC has the necessary levels of **expertise**	% survey respondents Externally: 75% Partners: 100%	Externally: agreed mostly or completely: **33%** Partners: **71%**	Consider having independent expert e.g. quality auditors with experience of non-interventional.
	Knowledge transfer and collaborative learning	Benefits of participating in the project outweigh the drawbacks	First year intent what to get qualitative responses from the survey participants ; for next year aim to quantitatively measure (the benefits should outweigh the difficulties)	Partner benefits: advanced knowledge, research capacities, collaborative work, synergies & sharing capacities (funds & data) Partner difficulties: set up roles and responsibilities, less control, public perception	Work with WP5 to clarify partners roles and responsibilities in DRIVE governance ; work on how to address public perception including IMI, ECDC, EMA and CSOs in a broader discussion about PPP

Participation / openness	**Stakeholders inclusion**	Key players are represented within the platform	% survey respondents Externally & Partners: 100%	Externally: stakeholders are appropriate: **89%** Partners: **100%**	Provide more detail about partners and collaborators on the website as this was requested. Increase involvement of patient organisations (requested multiple times).
	Information exchange flow - participation	There is good communication between partners	% survey respondents Partners: 100%	Partners: quite well very well **82%**	Better alignment of WP5 and WP7 and better communication between WP8 and rest of project. Increased number of meetings face-to-face
	Network creation	**Efforts** to on-board new research collaborators have been effectively carried out	% survey respondents Partners: 100% Tender sites selection report (WP2)	Partners: quite or very well **55%** **8 new research collaborators** through the 2018-19 tender + **1 PHI** (SSI)	Work with WP5 to raise awareness of the platform and how to get involved. Develop a strategy per country where appropriate.
	Leadership – decision making – conflict management	Appropriate review and approval of the study documents	% survey respondents Partners: 100%	Partners: quite well very well: **73%**	Consider having pre-defined timelines for WP7 deliverables review and dummy tables before results ; better anticipate the coming external communications /expected publications

		Conflicts are kept to a minimum and any that arise are well resolved	% survey respondents Partners: rarely encountered and 60% mostly or always resolved	Partners: encountered never or rarely 27% and mostly or always resolved 44%	Organise more face-to-face meetings.
Transparency	**Documentation**	Committees have access to relevant information	% survey respondents ISC & QCAC: 100%	ISC: mostly or completely **0%** QCAC: mostly or completely 5**0%**	Provide access to SharePoint. Invite ISC and QCAC to SC presentations for project update.
	Feedback (external -> internal)	Questions about platform governance are answered promptly	New comers feedback through tender process or more broadly	Not captured the first year – to be planned for the coming year/season	Consider asking new comers feedback regarding on boarding process and initial interactions in DRIVE
	Information flow to external stakeholders	DRIVE governance information is available on the website	External partners surveys about website	Not captured the first year – to be planned for the coming year/season	Consider asking external stakeholders feedback about transparency of the governance in the website after its update
		DRIVE governance is clear to external stakeholders and partners	% survey respondents Partners: 100% completely clear Externally: 100% somewhat or completely clear	Partners: 100% somewhat or completely clear Externally: 89%	Provide more details for the governance model image, explaining the roles and responsibilities of each DRIVE partners and DRIVE interactions with key external stakeholders or initiatives (e.g. EMA, ECDC, i-MOVE).
Scientific integrity/Ethics		The platform is perceived as being robust and	% survey respondents Externally: 75% Partners: 100%	Externally: Somewhat or completely appropriate: **56%**	Consider having 2 separate questions: one about the robustness of the results

		trustworthy in terms of delivering scientific results Scientific integrity is upheld through adequate firewalling measures	 % survey respondents ISC: 100%	Partners: **87%** ISC: completely adequate **50%**	(to be evaluated after the second season results will be communicated) ; another one on the trustworthiness of the governance. Discuss how to make WP7 reviews more transparent for external stakeholders. Consider improving the process flow for the WP7 deliverables review process and transparency of the EFPIA comments
Accountability/ responsibility	**Program accountability**	Deliverables for WP7 are provided on time	IMI reporting	0% of the WP7 deliverables submitted on time to IMI (4 deliverables)	Revisit deliverable deadlines to ensure they are in line with the usual timing of influenza epidemic and other project outputs.
	Process accountability	WP7 review process is well organised	% survey respondents ISC: 100%	ISC: quite or very well: 0%	Consider improving the WP7 review process (e.g. pre-defined timelines; ISC loop at first stage and EFPIA at second stage, consolidated EFPIA comments)
		Use of secondary data in DRIVE	Report	Not assessed – planned through the QCAC report for the second year	
	Financial	Budget allocated to	IMI Reporting	Documented in the financial	

	accountability **Monitoring evaluation and learning**	sites for data sharing Implementation of modification following previous evaluation	 Report - Survey	report Not yet assessed – planned for the second year	
Efficiency: Focus on the outcomes	**Resource allocation**	Allocation of the resources through the study platform (WP7, WP5, ISC, QCAC, WP8) The ISC is sustainable beyond the 5 years The QCAC is sustainable beyond the 5 years The platform and committees work efficiently	Report – Surveys ISC and QCAC % survey respondents Externally: 75% Partners & ISC: 100% % survey respondents Externally: 75% Partners & QCAC: 100% % survey respondents All: 100%	Need to evaluate what is the level of efficiency the second year based on first year feedback ISC (range from 3 to 15 hours per month for ISC and from 6 to 28 hours per month for QCAC) Externally: partly or completely: 22% Partners: 60% ISC: not very/no opinion 100% Externally: partly or completely: 33% Partners: 57% QCAC: 50% Partners: quite or very well: 82% ISC: 50% QCAC: 0%	Improve project management to decrease advisory members workload (e.g. timelines, meetings, update review process) Consider how the study platform may be sustainable and engage discussion with the advisory members Support QCAC in developing their work plan based on DRIVE expectations Involve ISC members in quality assessment scoring

		The site selection process is well organised	% survey respondents Partners: 90%	Partners quite or very well: 73%	development. Steering Committee to make final decision on fund allocation.
	Cost and outputs	The cost per center and ILI is appropriate	Report	Need to evaluate what is appropriate as benchmarks	Consider cost effectiveness of the study platform for the second year

Table 2: Analytic framework for governance evaluation

Thematic area	Topic	Broad questions	Methods	Targets
Legitimacy / Coherence	**Strategic vision**	- What are the objectives of the BSIVE platform? Is it valuable to have a sustainable platform to provide yearly brand –specific influenza vaccines effectiveness data in EU? Is a PPP necessary to build this kind of platform?	Perception - DRIVE partners and external stakeholders (Layer 1) surveys	Ensure that DRIVE partners have a common vision and collect external views about the legitimacy of building this platform Should be assessed throughout the 5 year project
	Consensus orientation	- Are key players' representations well balanced within the platform? How are decisions taken? How does the platform reconcile the different objectives of the various stakeholders in decision making? - What is the awareness of the platform governance (through true/false questions)? Do you think the mandates of the ISC/QCAC are clear?	Report Perception – DRIVE external stakeholders survey	Ensure that platform is appropriately designed for PPP Check the understanding of the platform governance and bodies' roles
	Capacity (competencies and professionalism)	- Do the members of the ISC/QCAC committees fulfil the needs? (representativeness and expertise) - Do the members of the ISC, QCAC have the required expertise for the roles? Could the ISC benefit from inclusion of additional experts/profiles?	Report Perception – DRIVE partners and external stakeholders surveys+ feedback	Identify potential gaps for expertise

Thematic area	Topic	Broad questions	Methods	Targets
			ISC from survey	
	Knowledge transfer and collaborative learning	- Describe the benefit to your organisation of taking part in the platform, and any difficulties you have encountered? What have you learned from working with the public or private sector?	Perception – DRIVE partners survey	Identify added value of collaboration
Participation/ openness	**Stakeholder inclusion**	Please list any stakeholders you think are missing from the platform?	Perception – DRIVE external stakeholders surveys	Identify potential gaps of representativeness
	Information exchange flow / participation	- What is the level of participation to meetings/TCs/reviews and what are the timeframes for access to documents/minutes deliverables - Indicate how easily and quickly documents produced by the platform are available to all members; are you satisfied with the way meetings are conducted (frequency and structure)	Report Perception – DRIVE partners survey	Determine the level of exchange and critical pathway of communication within the platform
	leadership/ decision making/ conflict managem	- Are the decisions made by the governance bodies aligned with their mandates? Are decisions made by committees effectively implemented? can you give example of situations where there has been conflict ; do you think they were well	Perception – DRIVE partners survey	Evaluate the perception of joint public and private projects

Thematic area	Topic	Broad questions	Methods	Targets
	ent	resolved/managed		
	Network creation	How were new associate partners on-boarded? Why did you accept to join the platform? Have you ever been professionally involved with vaccine manufacturers? Do you think efforts to on-board new research collaborators in DRIVE have been appropriately carried out? If you have the capacity to share data or carry out IVE studies, are you planning on joining DRIVE? What do you see as potential benefits/drawbacks?	Report – Perception – DRIVE ISC/QCAC surveys Perception – DRIVE partners survey Perception – external stakeholders survey	Determine how the platform is attractive
	Documentation	Is there good traceability of the documents and related reviews within the platform? - Do you think you have access to all relevant DRIVE info to carry out your work?	Report + ISC/QCAC feedback from surveys	Evaluate the review process

Thematic area	Topic	Broad questions	Methods	Targets
Transparency	Feedback (external -> internal)	What are the frequently asked questions about the platform governance? Were we able to provide clear & prompt answers?	Report	Determine the level of transparency through the interaction with potential new associate partners
	Information flow to external stakeholders	- What information is available on the DRIVE public website about the platform? Are major decisions taken within the platform appropriately communicated on the website? - How useful is the information on the DRIVE website for your organisation?	Report Perception - external stakeholders survey	Determine the level of transparency though the public website
Scientific integrity / Ethics	Check consistency with relevant guidances; application to WP7 studies	- Use what will be developed by subgroup1 & SOP2.2 &D3.2 + Does EFPIA review ensure adequate scientific independence? Do you think DRIVE des enough to facilitate scientific integrity? - Do you think the governance as proposed is appropriate to provide robust and trusted scientific results?	Report + ISC feedback from survey Perception - external stakeholders survey	Determine the level of scientific integrity
Accountability/	Program accountability	Are deliverables from the platform available on time (layer 1, EMA, website)	Report –	Determine the level of accountability

Thematic area	Topic	Broad questions	Methods	Targets
responsibility				
	Process accountability (deliverables, SOP)	Are the internal guidelines well followed? - How is the interaction with WP7? How well do you think the review process has been organised? Hoes well does the EFPIA review system work? - Data use by DRIVE is secondary, how does this affect the QCAC role?	Report Report – ISC feedback from survey Report- QCAC feedback from survey	
	Financial accountability	Is the budget allocated to sites for data sharing appropriately sized?	Report	
	Monitoring evaluation and learning	How well are evaluation results implemented?	Report ->starting the second year using baseline evaluation and related action plan	
Efficiency: Focus on the	Resource allocation	- What is the time spent by partners for relevant tasks/deliverables? Focus on WP7/WP5 ; What is the time spent by ISC on the project (overall and by deliverable) and QCAC (excluding evaluation?) + How much time do you generally spend on	Report + ISC QCAC feedback from surveys	Determine the level of efficiency

Thematic area	Topic	Broad questions	Methods	Targets
outcomes		DRIVE? Is it adequate to work with no monetary compensation? Do you think you work in an efficient way? Do you receive sufficient support? - Members of committees are reimbursed for travel but not paid for their time. Do you think it is appropriate and sustainable? What would be required for sustainability?	Perception – DRIVE external partners surveys + ISC/QCAC feedback from surveys	
	Cost and outputs	What is the total cost for one Influenza season per center and per ILI cases?	Report	