ANNUAL FORUM – FINAL EVENT
8 June 2022 - Brussels

Public poster session and experience sharing

DRIVE
Development of Robust and Innovative Vaccine Effectiveness

Collaborative framework and governance boundaries

Laurence Torcel-Pagnon (Sanofi) and Hanna Nohynek (THL)

On behalf of DRIVE WP1 (Alexandre Descamps - INSERM; Antonio Carmona - FISABIO ; Gael Dos Santos – GSK; Mendel Haag- SEQIRUS; Pieter Neels and Joris Vandeputte - IABS-EU; Nadia Vaenerberg - CoMO; Roberto Bonaiuti - UNIFI)

Background

- EMA requested vaccine companies to work jointly with public health institutes to provide yearly brand-specific Influenza Vaccine Effectiveness (IVE) estimates.
- IMI identified as a convenient EU umbrella, with a suitable legal, funding mechanism and framework for public-private governance. Guidance developed in previous IMI project (ADVANCE)* was used as a starting point for this proof of concept.

Objectives

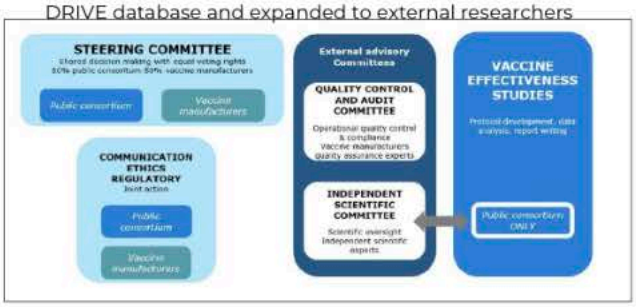
- Develop a **sustainable and transparent governance model** for joint brand-specific IVE Study through a public-private partnership under regulatory commitment.

Methods

- Development of a **monitoring and evaluation framework with key performance indicators.**
  - ➢ Conducting surveys and workshops to get feedback from DRIVE partners and insights from external stakeholders.

Results

- 5 consecutive influenza seasons of evaluation and monitoring
  - ➢ **72 responses from DRIVE partners, 43 from external stakeholders, 13 from governance committee experts**
- Adjustment of the governance model and streamlining of processes
  - ➢ Agile and relevant platform thanks to the yearly **public call for sites and their selection** supervised by key governance bodies
  - ➢ Independent study conduct and oversight of results interpretation by the **Independent Scientific Committee**
  - ➢ High quality standard ensured by the **Quality Control and Audit Committee**
  - ➢ Efficient and fruitful collaboration ensured by **joint brainstorming sessions, established mock report and streamlined process for scientific review**
  - ➢ **Open access for research data framework** developed for DRIVE database and expanded to external researchers



DRIVE Study platform governance

Assets & lessons learnt

- Despite transparency and safeguarding, **public-private partnership hesitancy** remains an obstacle for the scale up of such Real-World Evidence (RWE) collaborative platforms which should be tackled more broadly by EU and national institutions. **In the absence of relevant EU-level coordination of stakeholders' roles, responsibilities and investments, the DRIVE platform cannot be sustained after IMI project end considering the competitive environment (VEBIS ECDC public platform) on vaccines effectiveness.**

DRIVE study platform governance should be considered as a pioneering model for future RWE collaborative infrastructure in the EU for vaccines monitoring. However, no model can fit all initiatives and governance should be finetuned to the collaboration objectives and partners as illustrated by COVIDRIVE and PROMISE consortia.

Acknowledgement: This 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

*Torcel-Pagnon L et al. Vaccine 2019; 37(25): 3278-89

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DRIVE
Development of Robust and Innovative Vaccine Effectiveness

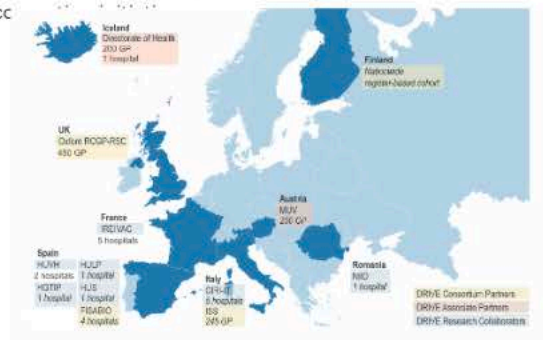
The evolution of DRIVE's study platform and site network

Antonio Carmona – FISABIO, Alexandre Descamps – INSERM, Anke Stuurman – P95

On behalf of DRIVE WP7 members (FISABIO, P95, THL, INSERM, UNIFI, ISS, U. Oxford, Azienda USL Toscana,, OPBG, UCBL), DRIVE Research Collaborators and Associate Partners

Background

- DRIVE's platform and study conduct has been fine-tuned since its first pilot season (2017/18) and the site network has progressively expanded over the years.
- **As of its last season (2021/22), DRIVE's study platform includes 21 hospitals and more than 1000 general practices in eight EU countries**, as well as one **nationwide population-based cohort, in Finland**.
- A **plateau in the network expansion** has been reached due to the COVID-19 crisis, PPP hesitancy and the existence of cc



DRIVE Study network for season 2021-22

Results

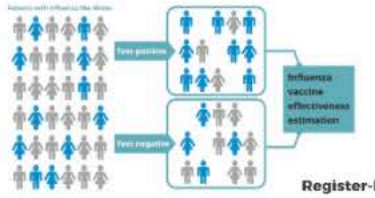
- DRIVE study accomplished **brand-specific IVE estimates for most influenza vaccines in the 2019/20 season - for 8 of the 11 vaccines** available in the European market.
- However, the **minimal influenza virus circulation**, together with the **shift of attention and resources** from flu to COVID-19, have largely impacted 2020/21 and 2021/22 seasons.

Flu season	2017/18	2018/19	2019/20	2020/21	2021/22
Features	High flu circulation	Moderate flu circulation	Moderate flu circulation – capped due to COVID-19	No flu circulation – COVID-19 pandemic	Very low flu circulation – Omicron wave and late peak flu
Study network	5 sites 4 countries +950 GP 4 hospitals	10 sites 7 countries 377 GP 12 hospitals	14 sites 8 countries 388 GP 19 hospitals	14 sites 8 countries +500 GP 25 hospitals	13 sites 8 countries +1000 GP 21 hospitals
Number of subjects	5.475 (TND) 288.655 p-y cohort	9351 (TND) 768.414 py cohort	9.077 (TND) 511.854 py cohort	7.025 (TND) 857.095 py cohort	6315 (TND) 836.622 py cohort
Number of LCI	2.844 (TND) 13.300 (cohort)	3339 (TND) 6379 (cohort)	> 3.500 (TND) > 2400 (cohort)	4 (TND) 25 (cohort)	1046 (TND) 331 (cohort)
BS IVE estimates	Yes, 4/11 but pilot season	Yes, 7/10 flu vaccine brands	Yes, 8/11 flu vaccine brands	No	Yes, 8/13 flu vaccine brands

Methods

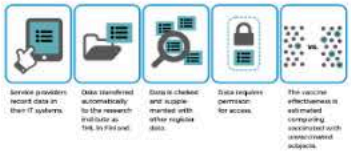
DRIVE Generic protocols

Test-negative studies



Hospital and Primary care

Register-based studies

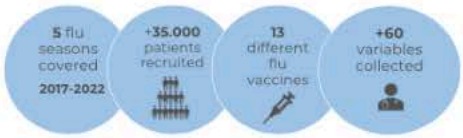


Finnish cohort

DRIVE Statistical Analysis Plan (SAP)

Assets

DRIVE Database



Development of a central IT platform for data collection and analysis

Study site network

- Agile and dynamic platform **annually expanded through the Call For Tenders**
- **Study implementation has been improved** thanks to the high-quality standards supported in DRIVE.
- Recurring sites acquired expertise in VE studies with DRIVE and we have built excellent **communication and relationships.**

Peer-reviewed publications and international conferences presentations

Lessons learnt

- Need to **increase sample size** by expanding the network, for more informative IVE results.
- **Development of eCRF** for data collection and quality checks would be an improvement
- Achieved **optimal timelines for IVE results report review** by public partners and EFPIA, mediated by the ISC (mock report, a huge facilitator)

DRIVE has developed an efficient study platform and a European-wide site network, enabling the study of pooled brand-specific IVE under a PPP framework

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DRIVE
Development of Robust and Innovative Vaccine Effectiveness

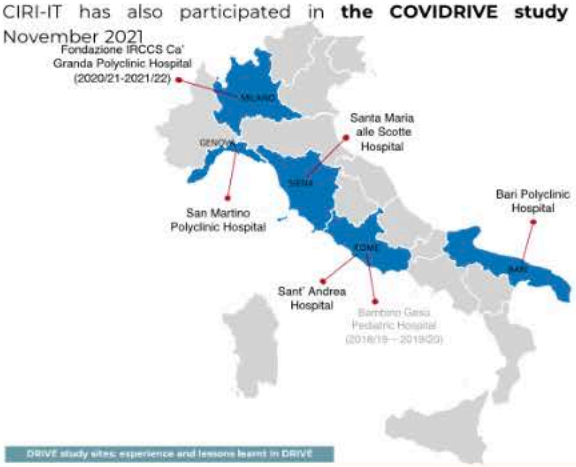
Sites perspectives: Experience in participating in IVE collaborative studies

Icardi G [1,2,3], Orsi A [1,2,3], Panatto D [1,2], Lai PL [1,2], Mosca S [2], Napoli C [4,5], Orsi GB [4,5], Torsello A [4,5], Chironna M [6], Loconsole D [6], Manini I [7], Pariani E [8], Castaldi S [8,9], Rizzo C [10], Bruzzone B [3], Domnich A [3], Ferrari A [1], Minet C [1], Iudica G [1], Parente F [1], Porretto M [1], Ricucci V [3], Simonetta D [1], Bertamino E [5], Bianco L [4,5], Bongiovanni M [1], Bubba L [8], Calcavecchia N [1], Cantova E [1], Garzillo G [1], Gatti G [1], Giberti I [1], Pennati BM [1], Pellegrinelli L [8], Spatera P [1], Trento G [1], Trombetta CS [1];
– 1 Department of Health Sciences, University of Genoa, Genoa, Italy; 2 Interuniversity Research Center on Influenza and other Transmissible Infections (CIRI-IT), Genoa, Italy; 3 IRCCS Ospedale Policlinico San Martino, Liguria Region, Italy; 4 University of Rome "La Sapienza", Rome, Italy; 5 Azienda Ospedaliero-Universitaria Sant'Andrea, Rome, Italy; 6 Department of Biomedical Sciences and Human Oncology, University of Bari, Puglia region, Italy; 7 Department of Molecular and Developmental Medicine, University of Siena, Tuscany Region, Italy; 8 Department of Biomedical Science for Health, University of Milan, Milan, Italy; 9 Fondazione IRCCS Ca' Granda Ospedale Maggiore Policlinico, Milan, Italy; 10 Bambino Gesù Children's Hospital, Rome, Italy.

Experiences

Since 2018/19, **CIRI-IT** has participated in the **DRIVE project**. The study has been conducted in various settings (primary care and hospital) and has included different age-groups. Since 2020-21, the DRIVE project has focused on adult and elderly hospitalized SARI patients. The **IT-BIVE-Hosp network** (including hospitals in Genoa, Bari, Rome, Siena and Milan) has been coordinated by CIRI-IT since 2019/20 .

CIRI-IT has also participated in **the COVIDRIVE study** since November 2021



DRIVE study sites: experience and lessons learnt in DRIVE

Improvements

During the last two influenza seasons, we have collected data from adult and elderly patients who are hospitalized with SARI. This is in contrast with the data collected by most national and international epidemiological and virological surveillance systems, which usually cover the entire population of patients presenting with either ILI or SARI symptoms, including children, in whom the circulation of influenza is much higher [Ruf and Knuf, 2014]. Even though influenza vaccination coverage rates are generally low among children, it is plausible that these rates will increase in this age-group in the future in Italy [Italian Ministry of Health 2021] and in various European countries [ECDC 2022] owing to recent changes in recommendations, which now promote universal pediatric vaccination. Future studies will therefore benefit from the inclusion of patients of **all age-groups** enrolled in **different settings** (hospital and primary care alike).

Lessons learnt

Studies conducted in real-word settings can be affected by unforeseen events. Indeed, the COVID-19 pandemic has affected the circulation of influenza and its surveillance systems. By first wiping out most other respiratory pathogens, including influenza, and subsequently changing their epidemiology, SARS-CoV-2 has altered the typical distribution pattern of respiratory infections [ECDC 2022]. Consequently, CIRI-IT has had to tailor its interventions according to the changed epidemiological scenario. This has been made possible by the creation of a **custom database platform** flexible enough to be updated in accordance with the DRIVE protocol, and by the use of advanced laboratory testing methods able to simultaneously detect a large spectrum of respiratory pathogens.

Sites' vision for DRIVE's future

Future studies should focus on the **prevention of respiratory infections as a whole**. Indeed, ILI, ARI and SARI caused by different pathogens share a similar clinical presentation. This is especially true of influenza, SARS-CoV-2 and RSV. Given that the **co-administration** of an age-appropriate influenza vaccine together with a COVID-19 vaccine is becoming a more common practice, and that combined vaccines are being developed [Domnich et al., 2022], it is important to be aware of possible interactions between infection and vaccine status with regard to different pathogens. Indeed, several studies have now demonstrated that vaccines designed for one specific pathogen may have **off-target effects** (e.g. trained immunity, bystander activation and cross-reactivity) that can impact infections by unrelated pathogens. These effects have been demonstrated for BCG (Bacillus Calmette-Guérin), measles, oral polio and, more recently, influenza, and may be mediated through both innate and adaptive immune-related mechanisms [Marín-Hernández et al., 2021].

These findings have opened the door to a new challenge in vaccinology: the development of trained immunity-based vaccines (TIbV) which, unlike conventional vaccines, aim to stimulate broader responses towards several pathogens [Sánchez-Ramón et al., 2018]. In addition, vaccines against RSV will soon be available for pediatric and elderly populations. In this context of change in the prevention of respiratory infections, it is important for the DRIVE network to tackle these prospective research issues and to broaden its focus to the vast spectrum of respiratory infections that can be prevented by vaccine technologies.

DRIVE should broaden its focus to a wider spectrum of respiratory pathogens, in order to evaluate the effectiveness of all vaccines that can prevent respiratory infections

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DRIVE
Development of Robust and Innovative Vaccine Effectiveness

Is publicly accessible data on influenza vaccine availability in the EU able to inform (brand-specific) influenza vaccine effectiveness studies?

Caterina Rizzo [a], Mendel DM Haag [b], Anke Stuurman [c]
[a]Bambino Gesù Children's Hospital, Rome, Italy and University of Pisa, Pisa Italy [b] Seqirus, Amsterdam, The Netherlands, [c] P95.
On behalf of DRIVE WP3: ISS, FISABIO, IRD, P95, UNIFI, THL, SURREY, OPBG, UCBL, SEQIRUS, GSK, SP), DRIVE Research Collaborators and Associate Partners

Background

The availability of sufficient vaccine coverage by brand is a key element for a targeted approach to study planning, site selection and to define feasibility.

Objectives

To inform the feasibility of using a mechanism of site selection based on prospective knowledge of vaccine brand availability in Europe.

Methods

- Structured telephone surveys
  - Oct 2017-Sep 2019
  - 10 public and 5 private stakeholder experts
- Review of public information sources on vaccine procurement

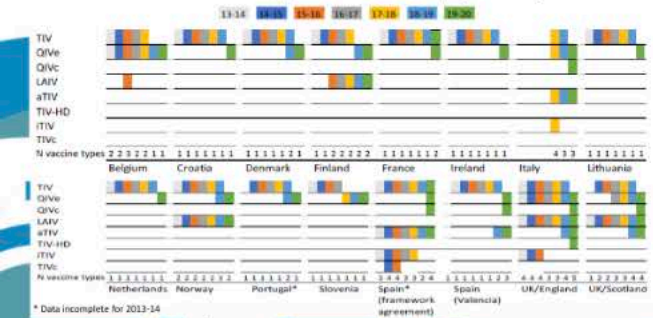
Table 1. Timing and public access of influenza vaccine tender award in EU countries

By calendar time of the year prior to the start of vaccination campaigns

Expected award of national public tender
Expected award of regional public tenders
Expected placement of majority of bookings by GPs
Expected placement of majority of bookings by pharmacies
Start of vaccination campaigns in 2019

Country	Contract duration	Data public?	Pop. size (M)	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov
Iceland	Annual	Yes	4.8														
Croatia	Multiyear (3)	Yes	4.1														
Netherlands	Multiyear (1+2)	Yes	17.2														
Denmark	Multiyear (1+2)	Yes	5.8														
Finland	Multiyear (1+2)	Yes	5.5														
Lithuania	Annual	Yes	2.8														
Scotland	Annual	Yes	5.4														
Norway	Multiyear (2+2)	Yes	5.3														
Slovenia	Annual	Yes	2.1														
Sweden	Multiyear	Partial	10.1														
Italy	Annual*	Yes	60.5														
Spain	Annual*	Yes	46.7														
England	Annual	No	56.0														
Wales	Annual	No	3.1														
France	Annual	No	66.9														
Belgium	Annual	No	11.4														
Germany	Annual	No	82.8														
Greece	Annual	No	10.7														

Table 2. Influenza vaccine types over seasons, by country



Results

Four main procurement systems are identified across 16 EU countries (Fig 1). Pre-season publicly accessible data on influenza vaccine procurement is limited (Table 1). Over time, an increasing number of influenza vaccine types have been procured, varying by country (Table 2).

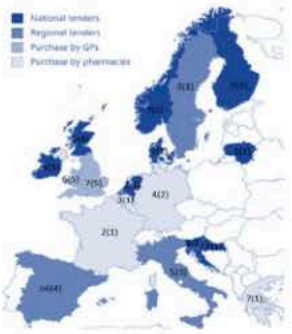


Figure 1. EU influenza vaccine procurement systems

X(Y): number of vaccine brands (number of vaccine types) in 2019/20

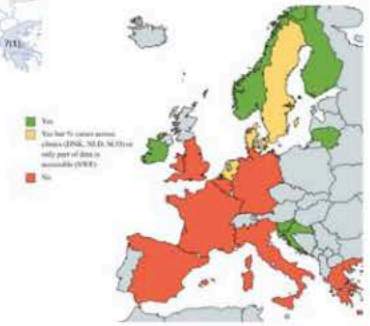


Figure 2: In conclusion: can public procurement information help determine ahead of campaigns which brand will be used where?

Assets & lessons learnt

Studies must cover multiple countries to capture all influenza vaccine brands. Study site selection based on prospective knowledge of vaccine availability is not shown to be feasible due to timing and accessibility of the vaccine tender award data. (Fig. 2)

Access to quality data on vaccination coverage for influenza and also other vaccine preventable diseases (i.e. COVID19) is needed at the EU level to inform vaccination programs and support vaccine effectiveness study implementation

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DRIVE
Development of Robust and Innovative Vaccine Effectiveness

Pragmatic approach to account for bias and confounding in test-negative design influenza vaccine effectiveness studies

Anke Stuurman P95 and Jos Nauta ABBOTT

On behalf of the authors (Miriam Levi UNIVERSITY OF ANTWERP, Philippe Beutels TUSCANY CENTRE HEALTH AUTHORITY , Helene Bricout SANOFI, Alexandre Descamps UNIVERSITÉ DE PARIS , Gaël Dos Santos GSK, Ian McGovern SEQIRUS INC, Ainara Mira-Iglesias FISABIO, Laurence Torcel-Pagnon SANOFI, Jorne Biccler P95)

Background

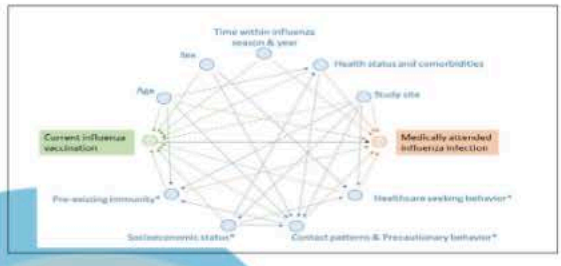
Influenza vaccine effectiveness (IVE) studies are observational studies and hence at risk of confounding. Elimination of confounding is done by including potential confounders in the statistical model**. Parsimonious confounder adjustment** can harmonize confounder adjustment and minimize data loss.

Objectives

To explore the impact of potential confounders on IVE in the DRIVE multi-country network of sites conducting TND studies.

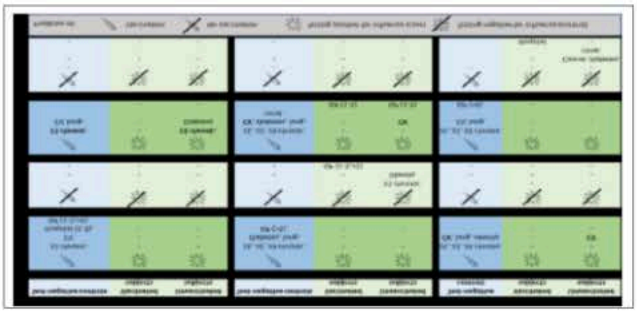
Methods

A **directed acyclic graph** (DAG) to map the relationship between influenza vaccination, medically attended influenza infection and confounders was constructed. The DRIVE data from the 2018/19 and 2019/20 seasons were used to explore the effect of covariate adjustment on IVE estimates. **The reference model** was adjusted for age, sex, calendar time and season. The **covariates studied** were present in at least one, two or three chronic diseases, present in six specific chronic diseases, and prior healthcare use. Analyses were conducted on-site and subsequently pooled.



Results

Across all age groups and settings, only **adjustment for lung disease in older adults in the primary care setting** resulted in a relative change of the IVE point estimate >10%.



Assets & lessons learnt

The **present study supports a parsimonious approach** to confounder adjustment in TND studies, limited to adjusting for age, sex and calendar time.

This approach has been applied by DRIVE since the 2019/20 influenza season to produce brand-specific IVE and report annual estimates to regulatory authorities.

Practical implications are that necessitating fewer variables lowers the threshold for enrollment of sites in IVE studies and simplifies the pooling of data from different IVE studies or study networks.

Submitted for publication.

A parsimonious approach to confounder adjustment in TND studies, limited to adjusting for age, sex and calendar time should be considered

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Interactions with regulatory authorities to address the EMA brand-specific requirement on seasonal influenza vaccines

Gaël Dos Santos (GSK), Pieter Neels (IABS EU) & Helene Bricout (Sanofi)

On of behalf of DRIVE regulatory working group (Kelly Hoffner – GSK, Laurence Torcel-Pagnon – Sanofi, Geraldine Solin – Sanofi, Ed Geuns - Abbott; Mendel Haag – Seqirus, Hazel-Anne Griffiths –Seqirus, Joris Vandeputte –IABS EU)

Background

- Manufacturers in DRIVE have licensed products under different licensure procedures (e.g., centralized vs de-centralized procedures) and thus have different points of contact for their regulatory obligations/submissions
- When DRIVE was launched, there were no standard mechanism to reach out to regulatory authorities as an "All consortium" and yet:
  - There was a need to standardize the criteria used to produce meaningful influenza vaccine effectiveness (IVE) data
  - There was a need for aligned and harmonized timing of submission and assessment of the data generated.
- Several topics had to be clarified with EMA/regulatory authorities:
  - Interactions with regulatory authorities on the seasonal EMA brand specific requirement on seasonal influenza vaccines
  - Expectations from EMA in terms of submission package (e.g., annual submission vs multi-year reports, data collected, sample size requirements, design specifications)
  - Sequence of the communications for the results and pathway for submission of reports by the manufacturers (e.g., Risk Management Plan update, Type II variation, etc.)
  - Potential role of EMA in facilitating cooperation among different stakeholders (ECDC, I-Move, other initiatives, etc.)

Objectives

- Seek annual guidance from EMA and member states representative to align upfront on expectations for vaccine performance evaluation and expected reporting from multi-Marketing Authorization Holders.
- Discuss shared challenges and hurdles in vaccine monitoring implementation and results interpretation, including the expectations from authorities about IVE robustness and what regulators consider as meaningful results for decision making

Method/Approach

- Since it began, DRIVE has engaged in regular interactions including with EMA and Vaccine Working Party (VWP) via annual meetings.
- EMA/regulatory representatives were invited to DRIVE annual forums
- National scientific advice was organized to seek guidance on the study design and statistical analysis plan
- A meeting was organized to discuss the post DRIVE landscape and way forward after the end of the project

Results/Outcomes

- Annual study reports have been jointly submitted to EMA by the DRIVE consortium on behalf of vaccine companies in DRIVE to fulfil their regulatory obligations.
  - For the 2017-18 and 2018-19 seasons, despite all efforts acknowledged by EMA/VWP, they concluded that IVE results were insufficient to allow a meaningful discussion with regulators.
  - After the 2019-20 season, via Scientific Advice, DRIVE obtained additional insights on:
    - Challenges to reach sufficient sample size to perform all stratified analyses in age groups and settings for all vaccine brands
    - The need to focus on populations with the highest disease burden with relatively high vaccine coverage and hospital settings
    - Limit the required number of confounders to be collected (parsimonious approach)
    - DRIVE requested for a Deferral to EMA on the annual requirement to generate brand specific vaccine effectiveness while roles & responsibilities at EU institution level are clarified

Assets & lessons learnt

- Attempt to routinely consult regulators to seek guidance and discuss the potential adjustments required
- Further continue to underscore the importance of clarifying the ultimate use of IVE data generated from a regulatory standpoint and potential implications for vaccination recommendations
- COVID-19 Pandemic redefined the order of priorities and increased the challenges of receiving feedback and guidance from regulators

DRIVE is considered a unique & pioneering proof-of-concept project, launched to address regulatory obligations
It is crucial to maintain close dialogue with regulatory authorities to set up expectations and (re)define priorities
In the future, the way to interact with regulators might drastically evolve with the EMA Innovative Task Force

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How to communicate influenza vaccine effectiveness by brand as outputs from a public private partnership

Júlia García-Bayarri- FISABIO, Riikka Rossi- THL, Hanna Nohynek- THL, Nadia Vaenerberg-CoMo

On behalf of DRIVE WP5 (Antonio Carmona-Fisabio, Alfredo Bonaiuti-UNIFI, Claudia Rivaldi-UNIFI,Alfredo Vannacci-UNIFI, Tamara Villarruel- Synapse, Uy Hoang- Oxfort University, Tala Martelli- CoMo, Pieter Neelse- IABS-EU, Joris Vandeputte- IABS-EU, Laurence Torcel-Pagnon- Sanofi, Emmanuella Dekonor- Seqirus, Sharon McHale- Sequirus, Gaël Dos Santos- GSK, Bram Palache- ABBOTT, Jos Nauta- ABBOTT, Caterina Rizzo- OPBG, Alexandre Descamps- APHP, Thomas Verstraeten- p-95

Background

DRIVE emerged as the result of an **EMA requirement to MAHs to estimate the effectiveness of the influenza vaccine (IVE) by brand**. This task required setting up a public private partnership (PPP), quite a unique governance model which had to deal with the hesitancy around results from initiatives that involve private partners.

Creating an ecosystem of **strong communication flow, transparency** and **easily accessible, understandable and re-usable information was crucial,** not only to disseminate the project results but also to explain the value and mechanisms of PPP and to ensure trust in those results.

Objectives

DRIVE communication strategy's **main objective** has been:

1. **Transparency**: make relevant information publicly available and accessible to different audiences.

2. **Raise awareness of influenza burden and complexity of accurately evaluating the performance** of each brand of influenza vaccine each year.

3. **Identify priority stakeholders**, adapt the information and its presentation to their needs and level of knowledge and involve them in the elaboration and revision processes.

For IVE the priority audiences are:

Policy	Government, regulators, PHI
Science	Academia, PHI
Industry	SMEs, Pharma
Society	NGOs, patient groups

Methods/Tools

Website	Oral presentations, posters
Articles, press releases, media, interviews	Newsletters
Scientific papers, summaries	Video and animations
Promotion materials	Event participation/organisation
	Social Media

Results

The DRIVE experience:

- Clear, transparent and targeted communication
- Translate and/or adapt contents to stakeholder specificities
- High quality content that values diversity
- Actively seeking opportunities for partnerships and collaboration and using team members' existing networks
- Team up with other EU projects and other stakeholders
- Organize and participate in events (online and offline)

73 website posts/press releases | **34** event participation/ organisation | **26** newsletters | **21** scientific publications | **6** promotional materials

Assets & lessons learnt

- Importance of providing **contextual information and put the results into the real-world evidence** perspectives and limitations.

- Communicating the importance of **cooperation within partners (PPP)**: To increase the feasibility and efficiency of the network to generate robust estimates.

- **Patient association cooperation** helps ensure accessibility

- **COVID-19 impact and future perspectives**: Need to adjust approach and adapt communication (E.g., after massive educational campaign derived from pandemic).

DRIVE faced a double challenge: present vaccine performance in real life settings and advocate PPP to ensure trust in those results

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