'DRIVE Deliverable D1.01 Multi Stakeholder Influenza Vaccine Effectiveness Research Agenda’

Form for collecting comments

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

# About DRIVE

The IMI JU project DRIVE (www.drive-eu.org) aims to create a European platform for studying brand-specific influenza vaccine effectiveness (IVE) and to develop a governance model for scientifically robust, independent and transparent studies in a public-private partnership.

In DRIVE, data from several independently operating national or regional study sites will be jointly analysed to obtain a large geographical coverage and sufficient sample size for brand-specific IVE estimation.

Decision-making in DRIVE is shared between public and private partners; however, the IVE studies themselves are led by public institutions without involvement of vaccine manufacturers and an Independent Scientific Committee oversees the process.

# Background

Influenza is a major public health burden. It is responsible for 50 million disease episodes and 15,000 to 70,000 deaths in the European Union (EU) and European Economic Area (EEA) Member States each year, although with considerable variation from season to season and by methodology used. Complications including deaths are more common in the elderly and in children younger than one year of age. Vaccination is considered as the most effective means for preventing influenza and its complications and the World Health Organization (WHO) has set a vaccination coverage target of at least 75% in the elderly population and among risk groups.

Due to frequent genetic and antigenic changes in influenza viruses, the seasonal vaccine is reformulated each year and annual revaccination is recommended. Observed IVE varies year-to-year due to a variety of reasons including mismatch between the vaccine virus strains and the circulating strains, waning immunity and possible interference from previous vaccinations. In the last two decades, controversies have sprung around the effectiveness of influenza vaccines. While past IVE estimation efforts have led to significant achievements using generic protocols, standard methodologies and laboratory confirmation, several questions about IVE remain open.

In its new guideline on influenza vaccines, the European Medicines Agency (EMA) requires that observational IVE studies be conducted in the EU/EEA as part of the post-licensure commitments of the vaccine manufacturers. EMA expects the studies to be conducted in line with Good Epidemiological Practice (GEP) guidelines and with European Network of Centres for Pharmacoepidemiology & Pharmacovigilance (ENCePP) guidelines; to reach this goal, manufacturers are encouraged to liaise with organisations/institutions/public health authorities.

# About the research agenda

The aim of the DRIVE project is to develop robust evidence on brand-specific influenza vaccine effectiveness (BSIVE) in Europe. This research agenda has been developed to identify areas where increased knowledge could support decision making for regulatory purposes and for public health programs. The agenda will be shared externally to solicit input that will be discussed with relevant stakeholders at the DRIVE Forum in Rome in September 2018. It will be updated annually to monitor research advances and possible new areas to investigate.

Aspects that could be researched to improve the robustness of estimates of influenza vaccine effectiveness have been delineated in terms of needs for evidence, in terms of data and methods, and in terms of governance. The needs for evidence are described according to the regulatory framework and discussed according to time, place and people. Robustness is described with the objective of improving grading of observational studies on IVE and BSIVE. The needs for data are described for exposure and outcome. A list of possible methodological investigations is proposed.

The section on governance discusses regulatory aspects of IVE and BSIVE, and the context of European collaborations in a post-authorization setting. It is proposed to develop key indicators for governance evaluation, explore the usefulness of existing standards to assess scientific independence and transparency of collaborative research, and evaluate the perception of public-private partnerships (PPPs).

Comments from:

| Name of organisation or individual |
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**General comments on the research agenda: e.g. can it be useful? Is the structure logical, completeness, priorities… could it be shared or hosted and maintained at EU level?**

|  | General comment |  |
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**Specific comments or suggestions on the text**

| Line number(s) of the relevant text*(e.g. Lines 20-23)* |  | Comment or suggestion  |  |
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Please add more rows if needed.

*When completed, this form should be sent electronically in Word format at* info@drive-eu.org before July 15th , 2018. The synthesis of contribution received will be posted on the DRIVE website.

*Please note that these comments and the identity of the sender will be published unless a specific justified objection is received.*