**Call for tenders – 2021/2022 influenza season**



**Measuring brand-specific influenza vaccine effectiveness in EU/EEA**

**Updated Proposal template**

*Completion of this template is required in order to apply to the Call for tenders of DRIVE. This completed form will be used for the evaluation and selection of the Research Collaborators by the Independent Scientific Committee and the Steering Committee of DRIVE.*

***Proposals should be submitted at the latest on May 14th 2021 by email to*** *info@drive-eu.org****.***

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| --- | --- |
| **Country/region(s) covered by the applicant proposal:** |  |
| **Affiliation and address of the applicant(s) and principal coordinator:**  |  |
| **Contact details of the applicant(s) or principal coordinator:****(email and phone number):** |  |

1. **Relevant expertise and experience of the applicant (s):**

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| --- | --- |
| **Expertise in conducting influenza vaccine effectiveness studies and/or influenza disease surveillance**  | Provide details of relevant projects/activities and related publications (up to five references)Please provide a description of the profile of the research team members who will be involved in the study and their experienceYou may provide supportive materials describing your capacity (protocols, article references, presentations etc.) |

1. **Proposed research collaboration for DRIVE**

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| **Ability to adhere to DRIVE generic protocols or level of appropriateness for DRIVE for innovative studies** | *Specify if your site has the capacity to implement the DRIVE generic protocols (as applicable TND or cohort) or if local adaptations are needed. Alternatively, please describe the rationale for innovative study design and the innovative aspect of your proposal (i.e. participatory epidemiology, novel data sources, endpoints…).**For any design, please provide a summary of the study design. Outline the population included (please note that* ***only applications focusing on the adult/older adult population will be considered****), provide a brief description of the clinical setting (please note that* ***only applications focusing on hospital setting will be considered****) in which the study is conducted, the strategy for the enrolment of patients or data collection (i.e. algorithm for inclusion of patients and procedures), the scheme for the specimen collection (per routine clinical practice, random or other) and any other specifics you consider important to share. For cohort studies using electronic medical records, please describe the source of data, the main data components and data linkage.* *Please indicate if the study is nested into the influenza surveillance scheme and whether this is part of the regional or national surveillance.* |
| **Updates in the protocol with respect to the previous season (if any)** | ***(Only to be filled for sites with experience participating in DRIVE studies (former members of DRIVE study sites network)*** *Updates in the local protocol with respect to the previous season (if any)* |
| **Ability to capture brand-specific information** | *Please detail the capacity to collect influenza vaccine exposure information (provide details on how this will be done if answer is Yes):** *Influenza vaccination status: Yes* ☐  *No* ☐
* *Vaccine type- or brand-specific information: Yes* ☐  *No* ☐
* *Date(s) of vaccination: Yes* ☐  *No* ☐

*Describe vaccination status collection source (please provide details for the options selected):** *Hospital medical records* ☐
* *Vaccine card* ☐
* *Vaccine registry* ☐
* *Patient interview (patient recall)* ☐
* *GP medical records* ☐

*Has brand information been captured in your previous studies (please provide a reference)?**Format:** *Electronic records* ☐
* *Paper records* ☐
* *A combination* ☐

*Specify national recommendations for influenza vaccination (list of targeted populations groups). If possible provide a link to the relevant online recommendations.**If available, provide information on which vaccine brand(s) are expected to be used for the 2021-2022 season in the locations where enrollment of subjects is anticipated. Please specify is this is based on either known tender awards for the 2021-22 season, and/or specification of the vaccine type in the tender, and/or consistent historical use of specific vaccine/type brands and/or in case of multiyear tender. Please indicate if specific tenders exist for specific age groups.*  |
| **Scientific reliability of the laboratory testing or ability to send samples for DRIVE testing** | *Provide details on laboratory testing: methods (current testing strategy in the hospital with respect to SARI cases), labs, tests: RT-PCR (commercial kit/multiplex), rapid antigen flu test; virus type (A vs. B) and subtype/lineage identification, sequencing capacity (Sanger/NGS)? Antigenic characterisation of influenza viruses?* *If testing facilities are not available at your institution, please explain your ability to send samples for testing in a DRIVE partner’s laboratory outside of your institution or country.**Describe participation of the laboratory in External Quality Assessment (EQA) and its results.* *You may provide supportive materials describing your capacity in this area (certificates, article references, presentations etc.)* |
| **Suitability of the data for the pooled analysis** | *Detail the level of data aggregation: specify if you can share individual anonymized data (preferred option) or aggregated data only; in case of aggregated data, confirm that you can provide them by at least age group (adults, older adults - mandatory)* *Confirm whether you can provide with the following minimum variables (mandatory variables):* * *Age: Yes* ☐  *No* ☐
* *Sex: Yes* ☐  *No* ☐
* *Date of symptom onset: Yes* ☐  *No* ☐

*Confirm whether you can provide optional variables, in particular, co-morbidities (see minimum dataset requirements table – optional variables): Yes* ☐  *No* ☐*Which of the optional variables is not feasible to be collected?* *Describe how you would collect the mandatory and optional variables (please provide details for the options selected):** *Hospital medical records* ☐
* *Patient interview (patient recall)* ☐
* *GP medical records* ☐
* *External medical records* ☐
 |
| **Estimated sample size and vaccine coverage** | *-Provide* ***influenza vaccination coverage rate(s)*** *for your target age group population(s) (at national level or regional/site level and by type or brand when available) (at least provide ranges >40%; [20-40%]; <20% per adult/elderly group). Provide the reference to the source of such information.* *- Detail study population including geographical representation, expected sample size and age distribution.* *- Provide the* ***number of SARI cases (and Laboratory Confirmed Influenza (LCI) cases among those SARI cases)*** *expected to be captured completing the table below. \*If possible, provide breakdown figures by vaccines type or brand for the season 2021-22 and specify the expected exposed case numbers.*

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|  | **Adults** | **Older adults** |
| **Hospital** |  **# SARI (# LCI)** *19/20 season* | **# SARI (# LCI)***19/20 season* |
| **# SARI (# LCI)** *20/21 season* | **# SARI (# LCI)***20/21 season* |
| **# SARI (# LCI)** *21/22 season (expected)* | **# SARI (# LCI)***21/22 season (expected)* |

 |
| **Current Influenza season managing** | *Please, detail how you have managed influenza and COVID-19 in terms of:* *- report on influenza 2020/21 season (number of LCI, date influenza surveillance activated (if)…)**- NPI measures put in place**-Screening/triage strategy and testing for influenza and COVID-19 cases (i.e. with the same swab or not, all SARIs systematically tested for influenza?, test simultaneously for influenza and COVID-19 in multiplex PCRs by standard of care? first SARS-CoV-2 test and then influenza? other approaches)*  |
| **COVID-19 variables** | * *COVID-19 case definition: Yes* ☐  *No* ☐
* *Lab test results of SARS-CoV-2 detection in a clinical specimen (type of tests)*
	+ *RT-PCR* ☐
	+ *Multiplex PCR* ☐
	+ *TMA* ☐
	+ *Antigen test* ☐
* *Clinical symptoms and diagnostic criteria to screen influenza and COVID-19 cases: Yes* ☐  *No* ☐
* *Availability to capture the use of antiviral treatment (treatment for COVID-19 or not): Yes* ☐  *No* ☐
* *Availability to capture co-morbidities to identify risk specific groups for COVID-19: Yes* ☐  *No* ☐
 |
| **COVID-19 vaccination** | *Please specify national recommendations for COVID-19 vaccination (roll out process, target populations prioritized, start dates of vaccinations). Provide information on which vaccine brand(s) have been used and are expected to be used for the 2021-2022 season. If possible, provide a link to the relevant online recommendations.**Please detail the capacity to collect COVID-19 vaccine exposure information:** *COVID-19 vaccination status: Yes* ☐  *No* ☐
* *Vaccine type- or brand-specific information: Yes* ☐  *No* ☐
* *Date(s) of vaccination: Yes* ☐  *No* ☐

*Describe vaccination status collection method (please provide details for the options selected):** *Hospital medical records* ☐
* *Vaccine card* ☐
* *Vaccine registry* ☐
* *Patient interview (patient recall)* ☐
* *GP medical records* ☐

*Format:** *Electronic records* ☐
* *Paper records* ☐
* *A combination* ☐
 |
| **Ethical considerations** | *If known, please provide the following information:**-If a separate Institutional Review Board (IRB) / Ethics Committee approval is needed.**-When the site needs to submit for approval to its respective ethics committee (month/week).**-How long the review takes (estimation).**-Which key documents need to be submitted (e.g. protocol, informed consent form, study synopsis…)* |

1. **Requested budget for DRIVE**

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
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| **Cost-effectiveness and level of possible co-funding from the applicant** |

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| *Provide a description of the costs for conducting the study completing the table below taking into account DRIVE budget rules: DRIVE provides catalytic funding only (level of co-funding is a criteria for selection), no funding for meeting participation beyond DRIVE (1 person per site for DRIVE Annual meeting attendance), no funding for data analysis and publication at site level (pooled analysis and publications are performed by P95 DRIVE partner), no funding for equipment or printing.* *\* Additional budget could be considered when specific efforts are proposed to collect COVID-19 related data.* |

**Budget table:**

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| --- | --- | --- | --- |
|  |  | **Covered by site** | **Requested from DRIVE** |
|  |  | **Person-Months** | **Budget (€)** | **Description** | **Person-Months** | **Budget (€)** | **Description** |
| **A. Personnel costs (€)**  |  |  |  |  |  |  |
| **B. Other Direct costs** | B.1 Travel and subsistence (€) |  |  |  |  |
| B.2 Consumables (€) (e.g. lab testing, PCR kits, subtyping, sequencing…) per SARI/LCI  |  |  |  |  |
| B.3 Other costs (€) (e.g. ethics committee fees, study and data management costs…) |  |  |  |  |
| **Total Direct Costs (€)** |  |  |  |  |
| **F. Indirect costs (€)**(max. 25% Total Direct Costs except Subcontracting) |  |  |  |  |
| **TOTAL BUDGET (€)** |  |  |  |  |

**Please list the other sources of funding/support:****Fixed Costs****Variable Costs** |

***In case of any question related to the call, please contact:*** *info@drive-eu.org*