**Call for tenders – 2020/2021 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 28th 2020 by email to*** [*info@drive-eu.org*](mailto: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)  Provide a short description of the profile of the persons who will be involved in the study |

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** | *Detail:*  *- For the conventional study design, specific 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 (only adult/older adult population will be considered), provide a brief description of the clinical setting (hospital) 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.*  *Please provide a description of the profile of the research team members, their experience, related projects /activities and related publications (up to five references)*  *You may provide supportive materials describing your capacity (protocols, article references, presentations etc.)* |
| **(Only to be filled for Research Collaborators with previous DRIVE experience): Updates in the protocol with respect to the previous season (if any)** | *(Only to be filled for sites with previous DRIVE experience): Updates in the protocol with respect to the previous season (if any)* |
| **Ability to capture brand-specific information** | *Detail:*  *- Capacity to collect vaccine type- or brand-specific information or alternative ways of recognizing type/brand (e.g. only one vaccine product used in the area). Describe vaccination status collection method (e.g. patient recall, electronic medical records, vaccine registry). Has brand information been captured in your previous studies (please provide a reference)?*  *Specify national recommendations for influenza vaccination (list of targeted populations groups). If available, provide information on which vaccine brand(s) are expected to be used for the 2020-2021 season. If possible provide a link to the relevant online recommendations.* |
| **Scientific reliability of the laboratory testing or ability to send samples for DRIVE testing** | *Provide details on laboratory testing: methods, labs, tests: antigen only, RT-PCR (homebrew/commercial/multiplex) - virus type (A vs. B), RT-PCR - subtype/lineage, RT-PCR + sequencing capacity (Sanger/NGS)? Antigenic characterisation of influenza viruses?*  *Are other respiratory viruses such as* ***SARS-CoV2*** *or RSV routinely detected simultaneously to influenza?*  *Or 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.)* |
| **Poolability of the data** | *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: age, sex and date of symptom onset.*  *Confirm whether you can provide optional variables, in particular, co-morbidities.* |
| **Estimated sample size and vaccine coverage** | *-Provide* ***influenza vaccination coverage rate(s)*** *for your target population(s) (at national level or regional/site level and by type or brand when available) (at least provide ranges >40%; [20-40%]; <20%). Provide the reference to the source of such information.*  *- Detail study population including geographical representation, expected sample size and age distribution.*  *- Provide estimated* ***number of Laboratory Confirmed Influenza (LCI)*** *expected to be captured completing the table below for the 2020-21 season (LCI/ILI or SARI by age (adults older adults). If possible provide breakdown figures by vaccines type or brand for the season 2020-21 and specify the expected exposed case numbers.*   |  |  |  | | --- | --- | --- | |  | **Adults** | **Older adults** | | **Hospital** | *# LCI (# ILI/SARI)* | *# LCI (# ILI/SARI)* |   *In each case, estimated number of LCI/ILI based on figures from the previous season (2019-20) adjusted by an estimated distribution* |
| **COVID-19 components** | *Because, COVID-19 is highly expected to impact IVE study, DRIVE will positively value the inclusion of COVID-19 data but it is not a requirement that will exclude a site during the selection process.*  *For instance:*  *-The triage* *strategy to screen influenza and COVID-19 cases (Test simultaneously for influenza and COVID-19 PCRs or other approaches)*  *-Variables to distinct clinical symptoms between the 2 diseases*  *-Death*  *-Co-morbidities to interpret BSIVE and identify risk specific groups for COVID-19*  *-Antiviral treatment 2 weeks upfront (treatment for COVID-19 or not) for potential confounders on IVE*  *-COVID-19 testing results (and type of tests).* |
| **Ethical considerations** | *If known, please provide the following information:*  *-If a separate Institutional Review Board (IRB) 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* |

1. **Requested budget for DRIVE**

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| **Cost-effectiveness and level of possible co-funding from the applicant** | |  | | --- | | *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 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 (e.g. testings).* |   **Budget table:**   |  |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | --- | |  |  | **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 (€) |  | |  |  | |  | | B.3 Other goods and services (€) |  | |  |  | |  | | **C. Subcontracting (€)** | |  | |  |  | |  | | **Total Direct Costs (€)** | |  | |  |  | |  | | **F. Indirect costs (€)**  (max. 25% Total Direct Costs except Subcontracting) | |  | |  |  | |  | | **TOTAL BUDGET (€)** | |  | |  |  | |  |   **Please list the other sources of funding/support:** |

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