	revision of study documents and the extension of the study and inclusion of additional study sites. The pilot study will inform the creation of a master protocol(s) for vaccine effectiveness/impact studies using health registries. The study design(s) will be discussed with ECDC considering the most appropriate methodological approach to address the research objectives and consider the time needed to obtain results. A study plan presented in the annual work plan of the lot will be submitted to ECDC for approval, additional aspects and decisions will be taken during the monthly conference calls.		
DL 4.2.3. EU/EEA master protocol for a study on vaccine effectiveness using health registries	The contractor will produce a protocol for a study on vaccine effectiveness using health registries, based on lessons learned from the pilot study (DL 4.2.2). This deliverable includes a statistical analysis plan for a pooled analysis. The protocol will include a codebook with a minimum set and the full list of variables to be collected; sample size calculations, matching algorithm for data originating from multiple health register and checking for duplicate data. The protocol will include standard operating procedures (SOPs) for recruitment of health care databases, study participants, data management, data checking and validation, reporting and data transfers, and data analysis, as annexes of the study protocol.	Four times during the duration of the framework contract	Word – ECDC template
DL 4.2.4. Proposed list of countries/sites joining the study	Based on the outcome of the landscape analysis (DL 4.2.1) and a list of countries initially identified by ECDC, the contractor will identify suitable study sites for performing the study. The proposed list (DL 4.2.4) will be based on a set of requirements for country/study sites to be eligible to the study and in particular the availability of suitable health outcome registries. The identified sites shall be able to implement the protocol(s).	Three times during the duration of the framework contract, in year 1, 2 and 3	Word
DL 4.2.5. Report describing all participating	Descriptive report. Standard template to be used across sites/cohorts. The report will include full list of participating countries/sites with a named focal point (“site”-specific study investigator), each health registry to be used, status of	Every two years	Word - ECDC template; Power point