Work package number [9]	WP3	Lead beneficiary [10]	7 - ISS
Work package title	Evaluation of studies' quality and feasibility		
Start month	1	End month	60

Objectives

To survey and collect data to support the evaluation of the quality and feasibility of the WP7 pilot studies for determining type/brand-specific seasonal influenza vaccine effectiveness.

Description of work and role of partners

WP3 - Evaluation of studies' quality and feasibility [Months: 1-60]
ISS, FISABIO, IRD, P95, UNIFI, THL, SURREY, UCBL, SP, SEQIRUS, GSK Bio
The WP Lead will be ISS and the WP Co-Coordinator will be SEQIRUS.

This WP will perform an assessment of the information on seasonal brand availability at clinical, regional or national levels and the related sources. It will also collect the local adapted protocols and assess differences, on the ethical submission process and the received feedback. Moreover, this WP will perform an evaluation of the pilot studies from a quality and feasibility perspective by developing quality and feasibility parameters and collecting this data from the study sites. The reports from WP3 will support the activities of the Committee for Quality Assurance and Control (see 3.2).

Task 3.1: Collection of information on the expected use of influenza vaccine brand.
Partners involved: P95 (Task leader), FISABIO, UNIFI, IRD, ISS, SURREY, SEQIRUS, SP, GSK (M1-60)

The availability of sufficient vaccine coverage by product is a key element to define the feasibility of measuring product-specific influenza VE and for study planning and site selection. The timing of the annual tenders for influenza vaccine purchases complicates the timely identification of countries or areas where a certain vaccine brand is to be used, and in which risk/age group.
To support the study tendering (task 2.7), we will survey information on available vaccine brand(s), distributed volume and brand specific coverage on different levels: national, regional and local -at the clinical level- from a wide range of parties involved in influenza vaccine purchase or distribution and able and willing to contribute information may be approached. Vaccine registries may also be considered as a potential source of this information. We will consider sources of information available pre-season as well as information on the actual vaccine brand during or post-season. We will also use of information on vaccine license status within each Member State and availability of vaccine distribution data from the EFPIA and determine which information can be shared in compliance with current competition laws. We will document which parameters are available depending on the source (timing of data availability, brand, lot, vaccination date or distribution date, personal identifiers etc).
The assessment of the available sources of brand information and the data contained herein will be crucial for planning purposes to allow a targeted approach to the selection of the locations where the study tenders (task 2.7) should be issued based on expected specific vaccine brand use and distributed volume and coverage. In addition, the analysis of geographic variability over various seasons and a clear picture on timing of availability of information on brand availability will be important to later determine if vaccine use by brand is predictable for future planning. It will also inform the feasibility of using a mechanism of site selection based on vaccine brand availability to support achieving brand specific vaccine effectiveness estimates for a wide range of brands. This will be Deliverable 3.1.
This task may involve surveys for example to identify pre-booking or purchasing intents from the healthcare professionals ordering influenza vaccines.
A collaboration with different projects (e.g. ECDC funded project VENICE III, IMI ADVANCE Project, Vaccine Europe, EFPIA) will be set to maximize the results obtained for each vaccine brand in the project.

Task 3.2: Assessment ethical submission process and differences in adapted protocols
Partners involved: UNIFI (Task leader), FISABIO, P95, ISS, SURREY, UCBL, SP, SEQIRUS (M6-60).

In this task, we will collect the local adapted protocols and informed consent and assess differences, on the ethical submission process and the received feedback. We will assess the applied ethical approval process (which ethical committees are used – i.e. local, institutional, national, the required documentation, timelines for the review) in participating countries and the feedback received from the ethics committees on the protocols each season. The assessment will pay specific attention to the elements of informed consent. Adapted local protocols will be collected and assessed for differences and the rationale for those differences.

Task 3.3: Operational Quality and feasibility evaluation of pilot studies.
Partners involved: ISS (Task leader), FISABIO, P95, UNIFI, SURREY, UCBL, SEQIRUS, SP, GSK (M6-60).

This WP will perform an evaluation of the WP7 pilot studies from an operational quality and feasibility perspective at the sight level by developing quality and feasibility parameters and collecting this data from the study sites through WP7 using the study support tool (task 2.6).
To identify for each study site selected to participate in the pilot studies methodological, organizational, logistical strengths, opportunities, limitations and gaps to conduct timely brand-specific vaccine effectiveness on a routine basis, we will assess the feasibility of the operational model after its implementation by developing a SWOT analysis for study sites in all levels (national, regional and local and at the clinical level). This will include data on strengths, weaknesses, and for identifying both the opportunities and threats of studies conducted. We will validate technical feasibility, study support application(s) implementation and identify potential obstacles to progress.
The results from the quality and feasibility assessments will be used to inform protocols (WP7), tools of WP2 (study support application, SOPs, site selection criteria and study tender process, laboratory tool implementation, sampling schemes) or analysis guidelines (WP4), but may likewise also require to evaluate adaptation of the quality management and feasibility criteria itself. We will also support the Committee for Quality assurance and control.
Parameters to evaluate the experience of the study sites with the governance, developed together with WP1, may be embedded in the site surveys.

Data on these criteria may be collected from the study sites through site visits, surveys or using the study support application of Task 2.6. This will be deliverable 3.2 and 3.5.

Participation per Partner

Partner number and short name	WP3 effort
1 - FISABIO	2.50
2 - IRD	2.00
3 - P95	2.70
4 - UNIFI	6.00
6 - THL	3.80
7 - ISS	15.00
8 - SURREY	7.00
10 - UCBL	5.20
12 - SP	4.00
14 - SEQIRUS	5.50
15 - GSK Bio	0.45
Total	54.15

List of deliverables

Deliverable Number[14]	Deliverable Title	Lead beneficiary	Type[15]	Dissemination level[16]	Due Date (in months)[17]
D3.1	Report on the sources for usage of specific influenza vaccine brands and accessibility	3 - P95	Report	Public	6

List of deliverables

Deliverable Number[14]	Deliverable Title	Lead beneficiary	Type[15]	Dissemination level[16]	Due Date (in months)[17]
D3.2	SWOT analysis plan and list of quality criteria	7 - ISS	Report	Public	8
D3.3	Report on the brand availability and usage of specific influenza vaccine brands	7 - ISS	Report	Public	12
D3.4	Report on the comparison of adapted local protocols and Ethical Committee evaluation in each study site	4 - UNIFI	Report	Public	12
D3.5	Written report on quality and feasibility evaluation	7 - ISS	Report	Public	14

Description of deliverables

D3.1 Report on the sources for usage of specific influenza vaccine brands and accessibility (M6, periodic updates);
D3.2 SWOT analysis plan and list of quality management components (M8);
D3.3 Report on the brand availability and usage of specific influenza vaccine brands (M12, periodic updates);
D3.4 Report on the comparison of adapted local protocols and Ethical Committee evaluation in each study site (M12, periodic updates);
D3.5. Written report on quality and feasibility evaluation (M14, periodic updates).

D3.1 : Report on the sources for usage of specific influenza vaccine brands and accessibility [6]

This report will be led by P95 and SEQIRUS, submmitted in M6 and periodically updated

D3.2 : SWOT analysis plan and list of quality criteria [8]

This deliverable will be co-led by ISS and SEQIRUS

D3.3 : Report on the brand availability and usage of specific influenza vaccine brands [12]

This report will be co-led by ISS and SEQIRUS, submmited in M12 and periodically updated.

D3.4 : Report on the comparison of adapted local protocols and Ethical Committee evaluation in each study site [12]

This report will be led by UNIFI and SEQIRUS, submmited in M12 and it will have periodic updates

D3.5 : Written report on quality and feasibility evaluation [14]

This deliverables will be led by ISS and SEQIRUS. It will be submmitted in M14 and periodically updated.

Schedule of relevant Milestones

Milestone number[18]	Milestone title	Lead beneficiary	Due Date (in months)	Means of verification
MS8	Sources of vaccine brand use identified	3 - P95	6	Milestone co-led by P95 and ISS. It will be verified through the sudmmission of Deliverable 3.1.
MS9	Annual brand availability	7 - ISS	12	Milestone co-led by ISS and SEQIRUS. Deliverable 3.3 submitted.

Schedule of relevant Milestones

Milestone number[18]	Milestone title	Lead beneficiary	Due Date (in months)	Means of verification
MS10	Initial SWOT analysis plan and list of quality criteria	7 - ISS	8	Milestone co-led by ISS and SEQIRUS. Deliverable 3.2 submitted.
MS11	All locally adapted protocols and ethics Committee evaluation received for each study site received	4 - UNIFI	10	Milestone co-led by UNIFI and ISS. List of all received adapted protocols available.