D3.2 SWOT analysis plan and list of quality criteria

777363– DRIVE

Development of Robust and Innovative Vaccine Effectiveness

WP3 – Evaluation of studies' quality and feasibility

Lead contributor	Valeria Alfonsi, Flavia Riccardo (8 – ISS)
	valeria.alfonsi@iss.it ; flavia.riccardo@iss.it
Other contributors	Caterina Rizzo (8 – ISS)
	Margarita Riera; Anke Stuurman (3 – P95)
	Miriam Levi (4 – UNIFI)
	Mendel Haag (14 – SEQIRUS)

Due date	28/02/2018
Delivery date	NA
Deliverable type	R
Dissemination level	PU

Description of Work	Version	Date
	V 0.4	26/02/2018

Document History

Version	Date	Description
V0.1	01/12/2017	First Draft
V0.2	19/01/2018	Consolidated Draft
V0.3	30/01/2018	Final Draft sent to SC for comments
V0.4	26/02/2018	New version addressing SC comments
V1.0	28/02/2018	Final deliverable
		Further revision by the QCAC when established

Index

Glossary

Opportunities	Elements in the environment external to the organization that the project could exploit to its advantage in meeting the objective.
Organization	Administration where the study team is located.
Operational model	In this context, this refers to how coutries make the DRIVE VE study protocol operational.
Strengths	Characteristics within the organization that are an advantage for the project in meeting the objective.
Study sites	All individuals/organization actively involved in performing the study at the national and project level.
SWOT Analysis	Structured planning method that allows to asses strengths, weaknesses, opportunities, and threats of any project/organization/activity.
Threats	Elements in the environment external to the organization that could cause trouble for the project in meeting the objective.
Weaknesses	Characteristics within the organization that would pose a disadvantage for the project in meeting the objective.

Publishable Summary

This document comprises of two sections: a SWOT analysis plan and a list of quality criteria.

The SWOT analysis is aimed at complementing the evaluation of the WP7 pilot studies from an operational quality and operational feasibility perspective at the site level. It will focus on strengths, weaknesses, opportunities and threats (SWOT) within each study site conducting the WP7 pilot studies aimed at acquiring timely brand-specific vaccine effectiveness data on a routine basis.

Three assessment axes will be considered: methodological, organizational and logistical, each with different target groups.

The results of the SWOT analysis 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) and analysis guidelines (WP4).

The list of elements of quality management that can be assessed through a possible additional survey were designed on the basis of the elements of quality management developed by the IMI ADVANCE project (Accelerated Development of VAccine beNefit-risk Collaboration in Europe) adapted to the DRIVE project implementation context.

Methods

SWOT analysis plan

A SWOT analysis is a structured planning method that allows to asses strengths, weaknesses, opportunities, and threats of any project/organization/activity. It allows to identify, with a consensus generating methodology, the internal and external factors that are favourable and unfavourable in achieving an objective [1]. It was originally developed to inform strategic decisions within industry, but has since been applied to a number of different contexts including public health [2].

A SWOT analysis can be used to [3]:

- Explore solutions to problems;
- Make decisions on how to best proceed towards an objective by identifying your opportunities in context of threats to success to clarify directions and choices;
- Determine where change is possible by making an inventory of your strengths and weaknesses to reveal priorities as well as possibilities; and
- Adjust and refine plans based on upcoming opportunities or unforeseen weaknesses and threats that could respectively open/close a path.

The analysis focusses on four elements that make its acronym: Strengths, Weaknesses, Opportunities, and Threats. For each objective, participants should list concrete/tangible aspects (in bullet points) pertaining to:

- **Strengths**: characteristics within the organization that are an advantage for the project in meeting the objective
- **Weaknesses**: characteristics within the organization that would pose a disadvantage for the project in meeting the objective
- **Opportunities**: elements in the environment external to the organization that the project could exploit to its advantage in meeting the objective

- **Threats**: elements in the environment external to the organization that could cause trouble for the project in meeting the objective

Strengths and Weaknesses focus on internal factors that can include the following [3]:

- Human resources - staff, volunteers, board members, target population
- Physical resources - your location, building, equipment
- Financial - grants, funding agencies, other sources of income
- Activities and processes - programs you run, systems you employ
- Past experiences - building blocks for learning and success, your reputation in the community

Opportunities and Threats focus on aspects that the organization is unable to define or control that can include the following [3]:

- Future trends in the organization's field
- The economy - local, national, or international
- Funding sources - foundations, donors, legislatures
- Demographics - changes in the age, race, gender, culture
- The physical environment
- Legislation
- Concomitant local, national or international events

However, it has been recognized that, when applied to the health sector, differences between strengths and weaknesses and between opportunities and threats remain somewhat arbitrary given its complex and dynamic context [4].

SWOT analysis are usually designed by project managers with a decision making role and are often carried out during workshops or retreats that enable participants to dedicate several hours to brainstorming and analysis of the situation.

In its most basic form it involves the following steps [4]:

1. Formulate external developments as opportunities or threats;
2. Formulate internal means and capabilities as strengths or weaknesses;
3. Confront strengths and weaknesses with opportunities and threats; and
4. Use the results to formulate strategic options.

While there is methodological consensus on these basic steps, applied methodological procedures are often diverse with SWOT-analysis articles presenting very different procedures in analysing data. Some analyses develop an essentially quantitative approach by comparing [5] or prioritizing content using weighted scoring systems, others are more qualitative [6].

In general, these two approaches are defined as: the *regulated SWOT* and the *organic SWOT*. The former identifies a set of rigorous rules (eg scoring systems) to structure the analysis, while the latter is more oriented towards flexibility. In the health sector the latter has been more often applied [4].

The driver towards the development of alternatives to the purely organic SWOT analysis are the three main types of limitations in the data that can be collected:

- Inadequate Definition of Factors (listing aspects that are too broad);
- Lack of Prioritization (that can risk thinking that a weak strength can counterbalance a major weakness); and
- Over-subjectivity/Compiler Bias (i.e. listing opinions not facts) [7].

The use of a scoring system has been tested in order to assign importance both to the content listed under the four SWOT elements (Strengths, Weaknesses, Opportunities and Threats) usually using quantitative or qualitative scales expressing 'probability of occurrence' and 'likely impact on the

organisation' [7, 8].

The SWOT analysis part of WP3 of the DRIVE project should identify, strengths, opportunities, weaknesses and threats (SWOT) at each implementation level and in all the study sites. It complements the evaluation of the WP7 pilot studies from an operational quality and operational feasibility perspective at the site level.

In order to design this SWOT analysis plan, the WP3 team comprising subject-matter experts in the field of influenza vaccine-effectiveness together with an expert with experience of SWOT methodology, have defined three main assessment axes. In those axes they identified the following elements that are relevant to conduct pilot studies on vaccine-effectiveness:

- Methodological,
- Organizational, and
- Logistical.

For each axis they then defined operational quality and operational feasibility parameters (Table 1).

Finally, they identified three different target groups involved in the implementation of the pilot studies at different implementation levels:

- Local (GP/hospital)
- Coordinator (National/Regional),
- Pooled analysis (Central level/Project level)

Each axis can include one or more operational quality and operational feasibility parameters.
Each target group can be involved in the assessment of one or more of the assessment axes, on the basis of the level of involvement in the pilot study.

Given the diversity of implementation of the pilot studies at study site level, in this phase of the project, the experts agreed to leave a measure of flexibility regarding the target group assignment to the axes in order to allow, if needed, a customization at study site level. Please refer ro Table 1 for a more clear and in depth understaning of the proposed axes and target group alignment.

In order to optimize the results of this assessment, following the end of the influenza season 2018/19, ideally a one-day workshop will be organized in each country that piloted the vaccine effectiveness study protocol in order to assess the quality and feasibility of the study operational model after its implementation. This will include qualitative data on strengths, weaknesses, and for identifying both the opportunities and threats of studies conducted.
However, the concrete and practical implementation of the SWOT workshops should be decided only after the VE study protocol will be defined and in place in each participating countries.
The workshops will be conducted through a CRO, but they will be subordinated to the resources available to the CRO.
Data on each identified SWOT objective will be collected during group work with participants belonging to the identified target groups for the SWOT analysis (Table 1). Each participant will be asked to compile an individual SWOT analysis and then a facilitator will combine the group inputs in a group SWOT analysis. The facilitator during this process will list elements of Strength, Weakness, Opportunity and Threat and for each listed element will collect:

1. The number of times participant had identifies that element in their individual SWOTs (N)
2. Reach with participants an agreement on the impact that the listed element could have on reaching the SWOT objective (using a scale from 1 very low to 5 very high) (I)

The SWOT analysis is a qualitative research relies on subjective judgment and cannot be fully quantified, but the research can uncover invaluable data due to its open collection process and allows researchers to develop hypotheses. This qualitative research tool examines internal factors (strengths

and weaknesses), and external factors (opportunities and threats). A comprehensive SWOT analysis goes insight into where the project has room to improve, and delivers with the foresight to adjust the VE protocol for the next seasons.

Each element listed in the group SWOT will be scored as N*I.

Facilitators conducting a SWOT analysis should be trained on the role they should hold during the event. Ahead of their specific training , facilitators received a facilitator guide in order to guide them in the conduction of the group work and improve the quality of the data collected.

While a SWOT analysis is a tool for auditing an organisation and its environment, it is not a stand alone auditing instrument, in particular in the field of health where audits typically also require a review of exising documents and an assessment of the allignement of current practice to existing protocols. It is therefore not to be considered in itself an audit.

Table 1 – Overview of the assessment axes, target group parameters and SWOT objectives proposed

Axes	Target Group	Parameter name	Parameter type (quality/feasibility)	SWOT Objective
Methodological aspects (the protocol implemented was able to…)	WP7/WP4	Harmonizing the data format	Quality	To increase uniformity of the data, to increase the efficiency of the data pooling and to reduce delays in data transfer and errors in merging and normalization different data sets
	WP7/WP4	Validation of exposure	Quality	To verify vaccination status through vaccination registers /health care records in a complete and correct way
	WP7	Pooled sample size from the national studies	Quality	To reach a study power able to assess brand-specific vaccine effectiveness
Organizational aspects	Study Sites at National Level	Human resources and training	Feasibility	To share principles and procedures among participating healthcare workers before the start, or at the end, of the study, and to avoid possible ambiguity in interpretation
	Study Sites at National Level and GP	Timeline	Feasibility	To avoid possible delays in collecting the needed information
	Study Sites at National Level	Sample size used during the pilot study	Feasibility	To reach a study power able to assess vaccine effectiveness and, possibly, brand specific vaccine effectiveness, also epidemic activity dependent, cumulative over years
	Study Sites at National Level/ GP	Validation of exposure	Feasibility	To verify vaccination status through vaccination registers /health care records in a complete and correct way
Logistical aspects	General Practitioners and Paediatricians	Sampling, storing and transport of throat/pharyngeal swabs	Feasibility	To reduce the number of inappropriate samples and reduce FN results.
	Study Sites at National Level/ GP	Data entry is harmonized (if appropriate)	Feasibility	To reduce delays in data transfer and errors in merging and normalization different data sets
	Study Sites at National Level/ GP	Adding additional data collection components on top of routine surveillance	Feasibility	To allow collection of data elements needed for brand specific VE

Elements of Quality management

The list of elements of quality management which can be assessed through a possible additional survey were included on the basis of the elements of quality management developed by the IMI ADVANCE project (Accelerated Development of VAccine beNefit-risk Collaboration in Europe) [11]. Defining elements of quality management rather than setting strict criteria as this can depend on the setting and allows more with a risk based approach to quality management.

The elements of quality management devised by the ADVANCE project [12] were assessed in relation to the DRIVE operational context (Annex 1- List of elements of quality management). This list has been adapted to the scenario where the sites follow the DRIVE developed procedures.

In particular, some aspects addressed in the criteria were found to be envisaged in the DRIVE project (e.g. having a study protocol). These were indicated under the heading "**PRE-DEFINED IN DRIVE PROJECT**" in the Table presented in Annex 1 of this report.

By contract, study sites should follow the DRIVE tools and protocols in the study implementation. All study sites should therefore by definition have those criteria in place. For this reason, in this case, it would be redundant to re-address them in a post study evaluation. This was specified under the heading "**COULD BE ASSESSED IN THE EVALUATION OF DRIVE STUDIES**" in the Table presented in Annex 1 of this report.

Notwithstanding this distinction, in case any of the study sites should follow their own applicable procedures, the full list of elements of quality management may be applied.

For all the included elements of quality management, on the basis of the DRIVE study structure, the implementation level (Project level/National level/ Subnational level) at which they would be best assessed was included.

Expected Results

We expect the SWOT analysis to assess the perceived quality and feasibility of the study operational model (see glossary) after its implementation for the different stakeholders involved at different implementation levels. This will include data on strengths, weaknesses, and for identifying both the opportunities and threats of studies conducted.

Conclusion

In conclusion, we expect to be able to validate the operational quality and feasibility of implementing timely brand-specific vaccine effectiveness on a routine basis and to 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) and analysis guidelines (WP4).

References

1. SWOT analysis. From Wikipedia, the free encyclopedia. Available from https://en.wikipedia.org/wiki/SWOT_analysis (latest access 28 November 2017)
2. Rajan D. Situation analysis of the health sector in Strategizing national health in the 21st century: a handbook. ISBN 978 92 4 154974 5 World Health Organization 2016
3. SWOT Analysis: Strengths, Weaknesses, Opportunities, and Threats [website] Community Toolbox available at http://ctb.ku.edu/en/table-of-contents/assessment/assessing-community-needs-and-resources/swot-analysis/main
4. van Wijngaarden JD, Scholten GR, van Wijk KP. Strategic analysis for health care organizations: the
5. suitability of the SWOT-analysis. Int J Health Plann Manage. 2010;27(1): 34–49 (http://onlinelibrary.
6. wiley.com/doi/10.1002/hpm.1032/full, accessed 16 January 2017.
7. Çınar F, Eren E, Mendeş H. Decentralization in Health Services and its Impacts: SWOT Analysis of Current Applications in Turkey. Procedia - Social and Behavioral Sciences Volume 99, 6 November 2013, Pages 711-718
8. Sperlich B, Düking P, Holmberg H-C. A SWOT Analysis of the Use and Potential Misuse of Implantable Monitoring Devices by Athletes. *Frontiers in Physiology*. 2017;8:629. doi:10.3389/fphys.2017.00629.
9. Pickton, D.W. and Wright, S. (1998). What's swot in strategic analysis? Strategic Change Vol. 7, pp. 101-109, 105-106
10. European Commission Joint Research Centre [Website] SWOT (Strengths Weaknesses Opportunities and Threats) Analysis. Available at http://forlearn.jrc.ec.europa.eu/guide/4_methodology/meth_swot-analysis.htm, accessed 16 January 2017
11. ADVANCE project Accelerated Development of VAccine beNefit-risk Collaboration in Europe [website] available at http://www.advance-vaccines.eu/ (latest access 31 January 2018)
12. ADVANCE project Accelerated Development of VAccine beNefit-risk Collaboration in Europe D5.9 White paper WP5 – Proof-of-concept studies of a framework to perform vaccine benefit-risk monitoring. V1.0 Draft, January 2018

Annex 1- List of elements of quality management

Elements of quality management **DEVELOPED BY THE ADVANCE IMI PROJECT**	**DRIVE PROJECT ADAPTATION**		
elements of quality management **THAT CAN BE ASSESSED THROUGH A SURVEY**	**LEVEL ADDRESSED IN DRIVE STUDIES (PROJECT LEVEL /NATIONAL LEVEL / SUBNATIONAL LEVEL)**	**PRE-DEFINED IN DRIVE PROJECT (Y/N)**	**COULD BE ASSESSED IN THE EVALUATION OF DRIVE STUDIES (Y/N)**
Study protocol			
A written final study protocol is established before study start.	Project level	Yes	No
A template is used for protocol development, compliant with applicable guidances.	Project level	Yes	No
Written documentation of relevant expert review of protocol is available	Project level	Yes	No
Required approval of regulatory agencies and/or	National level	Yes	No

Elements of quality management **DEVELOPED BY THE ADVANCE IMI PROJECT**	**DRIVE PROJECT ADAPTATION**		
elements of quality management **THAT CAN BE ASSESSED THROUGH A SURVEY**	**LEVEL ADDRESSED IN DRIVE STUDIES (PROJECT LEVEL /NATIONAL LEVEL / SUBNATIONAL LEVEL)**	**PRE-DEFINED IN DRIVE PROJECT (Y/N)**	**COULD BE ASSESSED IN THE EVALUATION OF DRIVE STUDIES (Y/N)**
relevant Ethics Committees (EC) is obtained prior to study starts and implementation of any amendment	In case studies are nested into surveillance system, no need for the EC approval In all other cases, approval of regulatory agencies required.		
Resources			
Declaration of interest statements are obtained	National level DoI obtained if needed	No	Yes
	National Level Responsibilities of each study team member are defined	No	Yes
Study personnel is trained on the latest versions of relevant study documentation before performing their duties.	National level	Yes	No
Ethics and Human (data) protection			
Signed confidentiality agreement of involved researchers	National level Signed confidentiality agreement might not be needed. Informed consent needed if the data collection is not embedded in the surveillance system	Not currently in DRIVE, however this will probably part of the new tender specification	Yes, only if relevant to Country context
Only personal data relevant to the study is collected.	National level	Yes	No

Elements of quality management **DEVELOPED BY THE ADVANCE IMI PROJECT**	**DRIVE PROJECT ADAPTATION**		
elements of quality management **THAT CAN BE ASSESSED THROUGH A SURVEY**	**LEVEL ADDRESSED IN DRIVE STUDIES (PROJECT LEVEL /NATIONAL LEVEL / SUBNATIONAL LEVEL)**	**PRE-DEFINED IN DRIVE PROJECT (Y/N)**	**COULD BE ASSESSED IN THE EVALUATION OF DRIVE STUDIES (Y/N)**
Data collection, transfer and processing			
Study specific procedures are documented in a Data Management plan	National level	No	Yes
Use of validated statistical software for data management (entry, transfer etc)	Project Level	Yes	No
A data storage index present for audit and inspection purposes	Project Level	Yes	No
Annotated programming maintained	Project Level	Yes	No
Back-up(s) of electronic data and records in different locations than the primary database	Project Level	Yes	No
Document management			
Standard templates of commonly applicable study related documents (at minimum protocol, statistical analysis plan informed consent, study report) and study specific procedural documents (project management plan, document management plan, data management plan, safety data management plan)	Project level	Yes	No
Written processes for review, approval and	Project level	Yes (to be verified)	No

Elements of quality management **DEVELOPED BY THE ADVANCE IMI PROJECT**	**DRIVE PROJECT ADAPTATION**		
elements of quality management **THAT CAN BE ASSESSED THROUGH A SURVEY**	**LEVEL ADDRESSED IN DRIVE STUDIES (PROJECT LEVEL /NATIONAL LEVEL / SUBNATIONAL LEVEL)**	**PRE-DEFINED IN DRIVE PROJECT (Y/N)**	**COULD BE ASSESSED IN THE EVALUATION OF DRIVE STUDIES (Y/N)**
versioning of any documents			
List of essential study documents	Project level	Yes (to be verified)	No
Analysis and Reporting			
Standardized compliant template for study reports	Project level	Yes	No
Annotated programming performed	Project level	Yes	No
Documented expert review	Project level	Yes	No
Security and storage			
Strong passwords are applied	National level	Yes (to be verified)	No
Encryption is applied when transferring protected health information	National level	Yes (to be verified)	No
Contracting			
Confidentiality and contractual agreements in place which defines the set of outsourced activities and timelines of deliverables	Project level	Not currently in DRIVE, however this will probably part of the new tender specification	No