



**Guidelines for
African swine fever (ASF) vaccines:
field evaluation and post-vaccination monitoring**



World Organisation
for Animal Health

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List of abbreviations

ASF	African swine fever
ASFV	African swine fever virus
DIVA	Differentiating infected from vaccinated animals
DPV	Days post-vaccination
ELISA	Enzyme-linked immunosorbent assay
LAV	Live attenuated virus
MRCT	Multisite randomised controlled trial
qPCR	Real-time polymerase chain reaction
RCT	Randomised controlled trial
WOAH	World Organisation for Animal Health

Glossary

Live attenuated virus

A virus that has been weakened in the laboratory to reduce its ability to cause disease while retaining sufficient viability to stimulate an immune response.

Randomised controlled trial

In the context of vaccine evaluation, a study that tests the effect of a vaccine candidate by randomly assigning individuals or groups to receive either the vaccine or a placebo.

Vaccine

Includes all products designed to stimulate active immunisation of animals against disease, without regard to the type of microorganism or microbial component or toxin from which they may be derived or that they contain.

Vaccine efficacy

Vaccine efficacy is a measure of how well a vaccine protects an animal against a specific undesirable outcome when **tested under environmentally controlled conditions**, where both the vaccination process and challenge infection are well defined. In addition to such environmentally controlled evaluations, vaccine efficacy can also be assessed under ideal field conditions through randomised controlled trials (RCTs), where animals (or groups) are randomly assigned to vaccinated and unvaccinated groups.

Vaccine effectiveness

Vaccine effectiveness is a measure of the protection provided against a specific undesirable outcome by comparing the incidence of that outcome in vaccinated and unvaccinated animals, adjusted for the probability of exposure. **It is measured under programme or 'real-life' conditions**, and it depends not only on the intrinsic quality of the vaccine, as supplied by the manufacturer, but also on extrinsic factors such as storage and distribution conditions, the match between the vaccine and circulating strains, the vaccination schedule, and, indirectly, on vaccination coverage, thus also evaluating the vaccination programme.

Wild type

The naturally occurring form of a virus.

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Main recommendations

These guidelines are intended for Veterinary Services, competent authorities and other stakeholders involved in the evaluation and potential implementation of African swine fever (ASF) vaccination programmes. They serve as a technical reference to support the design, implementation and evaluation of field studies, decision-making on vaccine deployment, and the monitoring of ASF vaccination programmes, taking into account local and regional conditions.

The key recommendations outlined in these guidelines are as follows:

1. Conduct field trials before authorising or deploying a new ASF vaccine, particularly where little information is available on its performance under field conditions.
2. Base any decision to introduce ASF vaccination on a clear national objective, such as reducing outbreaks, lowering mortality, limiting transmission or supporting recovery of disease-free status.
3. Perform randomised controlled trials in the field, where feasible, to evaluate vaccine safety and efficacy before launching a national or regional vaccination programme.
4. Provide relevant and comprehensive information to farmers involved in the trials and request their consent.
5. Ensure that field trials and vaccination programme monitoring are supported by an independent advisory committee with no conflict of interest in vaccine production, distribution or rollout.
6. Involve epidemiologists, statisticians, laboratory personnel, farmers and other relevant national stakeholders from the start of the study design through to the interpretation of results.
7. Use validated diagnostic methods and pre-defined case definitions to ensure that field trials and post-vaccination monitoring generate reliable results.
8. Once the vaccination programme is launched, integrate the ASF vaccination programme into a broader prevention and control strategy that also includes biosecurity, movement controls and surveillance. Vaccination should not be used as a stand-alone measure.
9. Establish a post-vaccination monitoring and pharmacovigilance system before vaccine rollout to detect side effects, adverse events and changes in vaccine performance as early as possible.
10. Put in place surveillance and genomic monitoring to detect possible reversion to virulence, recombination or changes in circulating ASF virus strains following vaccination.
11. Share field data and lessons learnt nationally and internationally, including through public-private partnerships and collaboration with other countries, to strengthen the evidence base for ASF vaccine use.

1. Introduction

African swine fever (ASF) is a transboundary disease caused by African swine fever virus (ASFV) that affects both domestic and wild pigs (Costard *et al.*, 2013; WOAH, 2025a). Originating in sub-Saharan Africa, ASFV has spread over the last decade to new countries in Africa, Asia, Europe and the island of Hispaniola in the Caribbean.¹ This has had a devastating economic impact on global pig production and food security in many countries, and the disease also threatens wild pig populations, local livelihoods, and animal health and welfare (Casal *et al.*, 2021; Luskin *et al.*, 2021). Until recently, there have been no vaccines considered effective for the control of ASF. While several vaccine candidates are under development, commercially produced live attenuated virus (LAV) vaccines have recently received regulatory approval for use in some Southeast Asian countries and are now being employed as part of ASF control strategies (Auer *et al.*, 2024; DOA – Bureau of Animal Industry, 2024; Nguyen, 2024). Other countries are also considering adopting these vaccines as part of their ASF control plans.

The importance of vaccine efficacy studies and post-vaccination monitoring in the field

In general, despite the large number of vaccines available for use against various animal diseases, research on the field evaluation of these vaccines is limited compared to that for human vaccines (Knight-Jones *et al.*, 2014). The evaluation and authorisation processes for veterinary vaccines, particularly for post-approval monitoring, are not completely standardised across all regions and are often less robust than those for human vaccines. This often results in less information being available to assess vaccine performance.

Consequently, for newer ASF vaccines with limited performance data available, it is recommended that field trials be conducted prior to vaccine registration in the country or region. This will help to ensure vaccine safety and efficacy before deployment in a national or regional vaccination programme. It is particularly important for vaccines that have not been previously tested in diverse locations or in various production systems and breeds. Unlike laboratory studies conducted under controlled experimental conditions, vaccine efficacy and vaccine effectiveness studies take place in more 'realistic' scenarios in the field, allowing the evaluation of different transmission routes, levels of exposure, time periods and variability between animals and farms that are not usually considered in laboratory trials.

Since ASF is a transboundary disease, an outbreak in one country poses a significant risk to its neighbouring countries. Therefore, there are key aspects to consider:

Shared responsibility and information exchange: Not all countries will have the capacity to conduct vaccine efficacy studies in the field. Information generated by other countries, both within and outside the region, should therefore be shared and made publicly available.

Adaptation to national contexts: The recommendations in these guidelines are intended as guidance and should be adapted to the specific needs and circumstances of each country. Where relevant, countries may also draw on examples or data from other settings.

¹ For up-to-date global animal disease information, please refer to the World Animal Health Information System (WAHIS) at <https://wahis.woah.org> (WOAH, 2025i).

2. Purpose, scope and use of guidelines

2.1 Purpose

The purpose of these guidelines is to provide WOAAH Members with the essential information required to perform systematic and reliable field evaluations of ASF vaccines (Figure 1). This will help generate ‘real-life’ and on-the-ground evidence to verify the quality parameters related to vaccine safety and efficacy as claimed by the vaccine manufacturers.

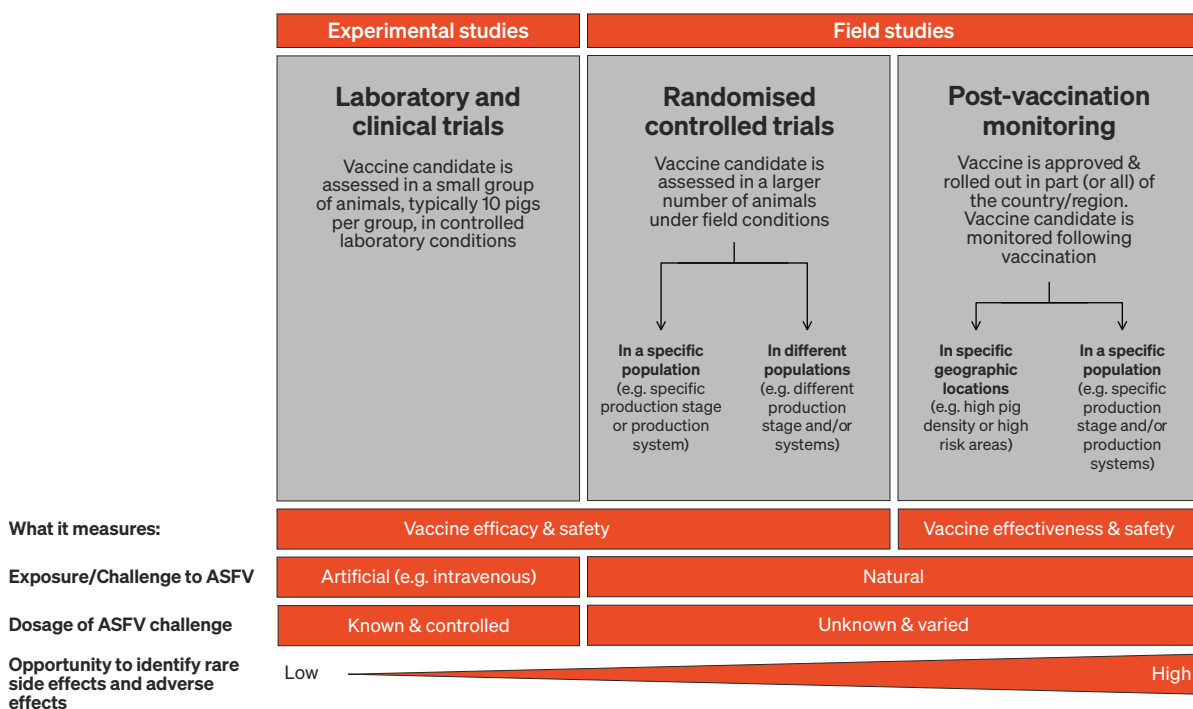


Figure 1. Schematic representation of the different types of studies to assess vaccine safety and efficacy, vaccine effectiveness and to conduct post-vaccination monitoring

Note: only the field study components are covered by these guidelines

2.2 Scope

These guidelines provide recommendations for the design and implementation of field studies to evaluate the efficacy and safety of ASF vaccines, as well as vaccine effectiveness and post-vaccination monitoring of vaccination programmes. They are intended to support WOAAH Members considering the use of ASF vaccination as part of national or regional disease prevention and control strategies.

Standards for the manufacture of safe and efficacious LAV vaccines for ASF have recently been adopted (WOAH, 2025b). Building on these standards, the guidelines in this document provide guidance for the subsequent stage of vaccine performance assessment. These guidelines assume that the vaccine candidate has already undergone assessment for safety and efficacy in small, controlled experimental studies (Figure 1), as described in Chapter 1.1.8 ‘Principles of Veterinary Vaccine Production’ (WOAH, 2025c) of the *Manual of Diagnostic Tests and Vaccines for Terrestrial Animals* (hereafter referred to as the *Terrestrial Manual*).

At the time of writing, there are no widely recognised ASF vaccines that have demonstrated strong effectiveness under field conditions. Currently, only LAV ASF vaccines are authorised for use. Although these guidelines are relevant to all vaccine types, they primarily focus on LAV vaccine evaluation.

It is therefore recommended that the guidelines be reviewed and adapted in the future, as new vaccine types are being developed.

Furthermore, these guidelines apply only to domestic pigs (*Sus domesticus*). Although wild pigs are susceptible to ASFV, and LAV vaccines have been proven effective in controlling and preventing the spread of other diseases in certain wild species (Hernandez, 2020), any strategy to vaccinate wild populations against ASF requires separate *ex situ* studies to assess efficacy and ensure that there are no unintended consequences.

These guidelines strongly recommend that ASF vaccines should only be considered for use as part of a national or regional vaccination programme, or be made commercially available, following thorough field evaluation. This evaluation should involve an independent advisory committee with no conflict of interest in vaccine production, distribution or rollout.

It is strongly recommended to involve an epidemiologist and/or a statistician with experience in the design and analysis of randomised controlled trials (RCTs) and pharmacovigilance.

Relevant national stakeholders should also be involved throughout the field evaluation.

WOAH promotes collaboration between the public sector (Veterinary Services and Veterinary Authorities), the private sector (private veterinarians, the pig industry and vaccine manufacturers), and across countries, and highlights the importance of transparency in data sharing (see Article 1.1.5. of the *Terrestrial Animal Health Code* [WOAH, 2025d]).

2.3 Target audience

The target audience for these guidelines includes Veterinary Services and competent authorities involved in the regulatory approval of veterinary vaccines in regions where ASF vaccine rollout is being considered.

These guidelines provide considerations that can be adapted to the local circumstances and requirements of each country or region at the time of implementation, with examples included where possible. It is important to consider the purpose of the anticipated vaccination programme in relation to the local or regional objectives for the prevention and control of ASF.

2.4 How to use these guidelines

These guidelines provide the necessary tools and practical advice for conducting vaccine trials in the field prior to the authorisation of a national vaccination programme and before vaccine rollout (**Figure 2**).

Section 3 provides guidance on how to conduct vaccine efficacy studies in the field through RCTs. This section includes various study designs and statistical analyses, along with working examples where possible.

Section 4 presents an overview of risk–benefit analysis, which should be conducted to assess whether the benefits of an ASF vaccination programme outweigh the potential risks in each country or region, considering local characteristics and resources.

Section 5 provides guidance on how to conduct post-vaccination monitoring and evaluation, as well as how to design and perform vaccine effectiveness studies.

The **Annexes** contain ready-to-use tools for sample size calculation and templates for sample collection during field trials to help users apply these guidelines in the field.

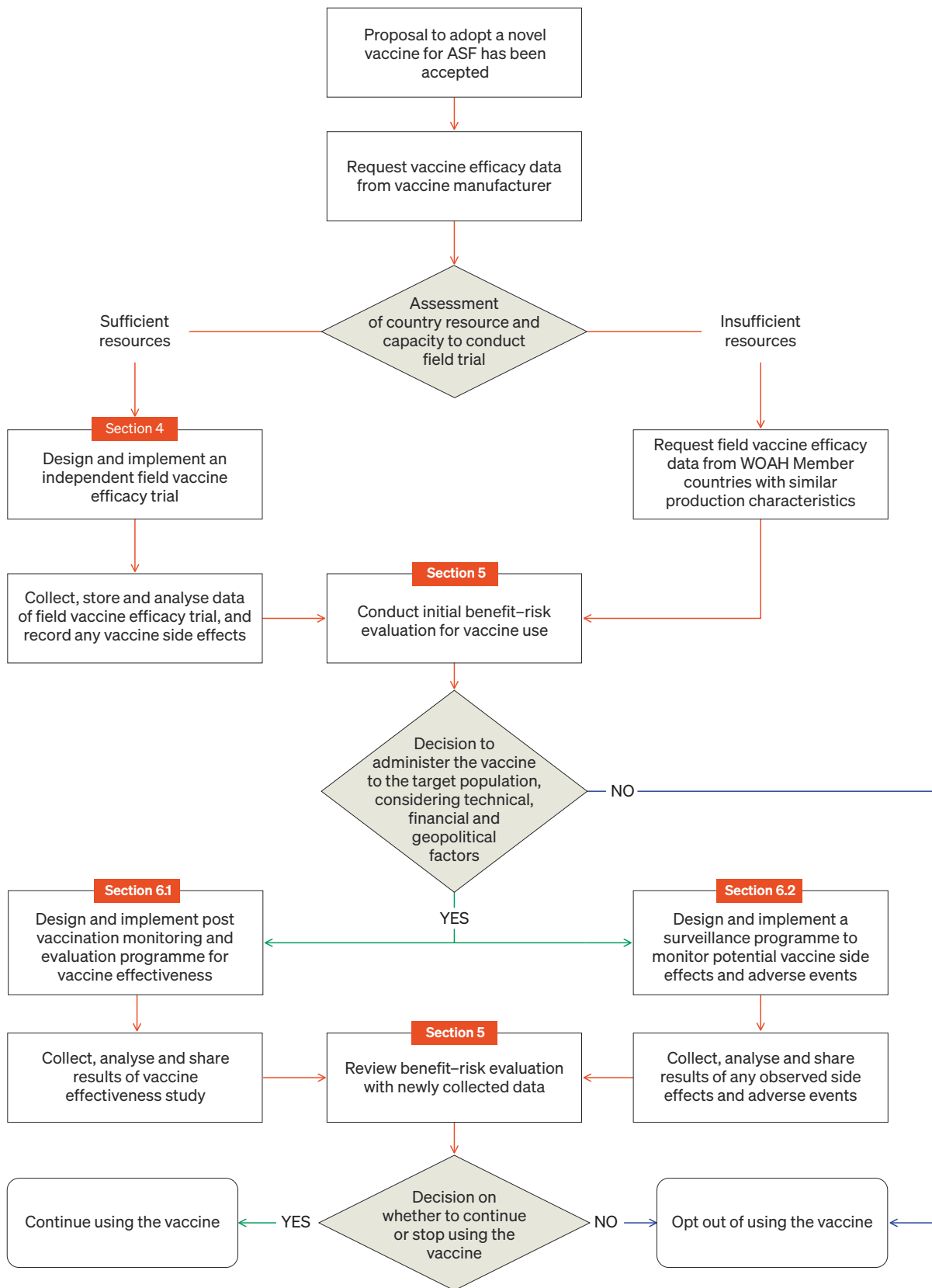


Figure 2. A schematic representation of these guidelines and the links between different sections

2.5 Further resources

Technical support and advice on study design and data analysis can be sought from WOAAH, which can connect countries with the relevant WOAAH Reference Laboratory or Collaborating Centre.

These guidelines should be used in conjunction with the following documents:

International standards for ASF prevention and control

- *Terrestrial Code*, [Chapter 15.1](#). Infection with African swine fever virus (WOAH, 2025b)
- *Terrestrial Code*, [Chapter 4.18](#). Vaccination (WOAH, 2025f)

Laboratory diagnostics and pathogen detection

- [Manual of Diagnostic Tests and Vaccines for Terrestrial Animals](#) (WOAH, 2025g) (hereafter known as the *Terrestrial Manual*)
- *Terrestrial Manual*, [Chapter 3.9.1](#). African Swine Fever (Infection with African Swine Fever Virus) (WOAH, 2025a)
- [Addressing African swine fever: Guidelines for Laboratory Diagnosis](#) (WOAH, 2024)

Guidance on vaccine evaluation and clinical trials

- [Guideline on clinical trials with immunological veterinary medicinal products](#) (EMA, 2022a)
- [Guideline on statistical principles for clinical trials for veterinary medicinal products](#) (EMA, 2022b)
- [Guideline on the evaluation of the benefit-risk balance of veterinary medicinal products](#) (EMA, 2024)

Post-vaccination monitoring and pharmacovigilance

- [How to set up a pharmacovigilance system for veterinary medicinal products](#) (WOAH, 2022)

Policy guidance on ASF vaccination

- [WOAH statement on ASF vaccines](#) (WOAH, 2025h)

Data sharing

Data sharing is essential for promoting transparency, enabling secondary analyses, and strengthening the evidence base for decision-making. Greater openness and data sharing should be encouraged in accordance with Article 1.1.5. of the *Terrestrial Code* (WOAH, 2025d).

It is important to acknowledge that there are valid concerns that may limit the extent of data sharing, particularly when field trials are sponsored or conducted by vaccine manufacturers. In such cases, commercially sensitive information may be involved, and data sharing may be constrained by confidentiality agreements or national legal and regulatory frameworks.

Public–private partnerships (PPPs) are encouraged to facilitate transparency, including through the publication of summary reports where full data disclosure is not feasible, to share meaningful insights on vaccine field performance while acknowledging limitations in access to underlying data.

3. Evaluation of African swine fever vaccine efficacy and safety in the field

3.1 Case definition

Before designing a vaccine efficacy study, the case definition for ASF should be clearly defined. Infection with ASFV can result in a wide range of clinical manifestations, ranging from peracute or acute to chronic disease and subclinical infections. Such variability can make it difficult to rely on clinical signs alone.

[Chapter 15.1](#) of the *Terrestrial Code* (WOAH, 2025b) defines ‘infection with ASFV’ for official reporting as either the isolation of ASFV from a suid or the detection of antigen, nucleic acid or antibodies specific to ASFV from an animal, in addition to current or recent ASF clinical signs (or an epidemiological link to a confirmed case). However, this case definition was established when ASF vaccines were unavailable, and the detection of virus or antibodies alongside clinical signs would strongly indicate current or recent ASFV infection. The introduction of ASF vaccines complicates the use of this definition due to potential vaccine-related viral shedding and post-vaccination side effects, particularly where these may differ by breed, age, production system, level of biosecurity or where other diseases or viruses are present on the farm or in the region.

For vaccine evaluation, the case definition specifies the criteria by which cases are identified and counted, based on indicators of protection (e.g. mortality, severe clinical signs or transmission; see [Figure 3](#) in [Section 3.2](#) for examples).

The following complementary information may support the development of a clearer case definition:

- i) Knowledge of circulating ASFV strains is key to recognising the clinical signs associated with the infection, as these may vary depending on the infecting strain.
- ii) History of any previous ASF vaccination (official or unofficial) and/or ASF outbreaks in the study location. Vaccines, especially those that have not been approved, may mask clinical signs of infection or show unpredictable variability in protection.
- iii) Presence of other swine diseases causing similar clinical signs (e.g. classical swine fever, porcine reproductive and respiratory syndrome, porcine circovirus, porcine epidemic diarrhoea).

It is recommended that a baseline survey be conducted prior to, or at the start of, a vaccine efficacy study to collect information on the baseline health status of the pig population, including the collection of blood samples for serological and molecular analysis. This information can then be used to inform the case definition for the study, which may vary across epidemiological scenarios and may differ from the case definition used for other purposes, such as for official disease notification.

To support the application of the case definition, a scoring system of clinical signs may be adopted, taking into account the factors described above in the local context and the findings from the baseline survey. An example scoring system of ASF clinical signs is presented in [Table 1](#). Trained observers can be provided with a list of criteria to evaluate individual pigs or herds, with scores summed to indicate disease severity. A suspected case of ASF may be defined when the score exceeds a pre-defined threshold (e.g. 10), after which further confirmation may be required.

Table 1. An example scoring system for ASF clinical signs at the individual pig level, used in studies conducted at Wageningen University (de Carvalho Ferreira *et al.*, 2012)

Type of clinical signs	Description	Score
Liveliness	Reduced liveliness, stands up without help	1
	Sluggish but stands up when helped	2
	Dormant; will not stand up	3
Posture	Stiffness and bent back when standing up; posture progressively corrects	1
	Stiffness and bent back remain	2
	Cramps (abdominal pain)	3
Body shape	Empty stomach (sunken flanks)	1
	Empty stomach with significant weight loss	2
	Wasting (ribs and vertebrae visible; long hair)	3
Breathing	Increased respiratory rate	1
	Significantly increased respiratory rate; abdominal breathing	2
	Difficult breathing (open mouth breathing), wheezing, coughing	3
Neurological signs	Somewhat unsteady gait, quickly corrected	1
	Ataxia/paralysis of the hindquarters; can still walk	2
	Paralysis of the hindquarters; unable to stand; convulsions	3
Skin (particularly ears, snout, tail, legs, abdomen)	Red skin	1
	Blue-purple discolouration of the skin; occasional skin bleeding	2
	Large blue/black spots; cold skin; large subcutaneous bleeding; skin necrosis/ulceration	3
Appetite	Eats slowly	1
	Shows interest in food but eats little or nothing	2
	Will not eat; has no interest in food	3
Defecation	Slightly reduced amount of faeces; dry stools	1
	Reduced amount of faeces or diarrhoea	2
	No faeces or watery/bloody diarrhoea	3
Ocular/nasal discharge	Thin discharge from nose and/or eyes (without admixture)	1
	Thick discharge from nose and/or eyes (no blood)	2
	Bloody discharge from nose and/or eyes	3
Vomiting	Occasional emesis (once during the observation period)	1
	Repeated emesis (several times during the observation period)	2

3.2 Outcome measures

Before conducting a field vaccine efficacy study, the outcomes of interest must be clearly defined to guide key elements of the study design. Study outcomes should reflect the main objective of the intended vaccination programme within the context of the country's national or regional ASF control programme, where goals may differ between regions or production systems. Consequently, outcome measures should be selected based on these goals, with some measures prioritised over others (Figure 3). The outcomes should also be linked to the case definition and to the measures of vaccine efficacy demonstrated in previously conducted controlled experiments.

Scenario 1 Region where ASFV is endemic	Scenario 2 Region previously ASF-free, where ASF is newly detected
<p>Objectives of the national ASF control programme:</p> <ul style="list-style-type: none">• Reduce the number of ASF outbreaks• Minimise associated production impacts <p>Objectives of the vaccination programme:</p> <ul style="list-style-type: none">• Decrease ASFV transmissibility• Reduce associated morbidity and mortality rates <p>Case definitions:</p> <ul style="list-style-type: none">• A clinical sign score of 10 or above (See Table 1)• Pig health deviation from baseline health survey <p>Outcome measures of the vaccination programme:</p> <ul style="list-style-type: none">• New cases of ASF (based on case definition)• Change in production parameters (e.g. weight)• Variations in morbidity or mortality rates	<p>Objectives of the national ASF control programme:</p> <ul style="list-style-type: none">• Regain ASF-free disease status <p>Objectives of the vaccination programme:</p> <ul style="list-style-type: none">• Decrease ASFV transmissibility• Assist in eradicating ASFV from pig population <p>Case definitions:</p> <ul style="list-style-type: none">• At least two clinical signs consistent with ASF, along with the detection of antigen or nucleic acid specific to ASFV <p>Outcome measures of the vaccination programme:</p> <ul style="list-style-type: none">• New cases of ASF (based on case definition)

Figure 3. Two examples of regions with different outcome measures for vaccine efficacy studies, based on the region's situation and the goals of the ASF control programme

These details are illustrative only, and countries should take into account their local contexts. Different regions within the same country may have differing objectives and outcomes, depending on their ASF status

3.3 Study design

i. Randomised controlled trial designs

RCTs are generally considered the gold standard method for evaluating vaccine efficacy (Dean *et al.*, 2019). They compare at least two groups (often referred to in the literature as ‘arms’), in which one group receives the vaccine candidate under assessment, while the other usually receives a placebo (or a vaccine for a different disease). These trials can vary in design depending on the objectives and available resources and can be conducted at either the individual (pig) or cluster level (e.g. pen, farm or village).

When randomisation occurs at the individual level, it typically requires smaller sample sizes; however, it assesses only the direct effects of the vaccine and does not account for variability between farms. Therefore, randomisation at the individual level may underestimate overall vaccine efficacy (**Table 2**).

In contrast, randomisation at the cluster level provides insights into both direct and indirect effects, i.e. the reduction in cases at the population level and, consequently, the source of transmission, leading to a reduced risk of infection in the study population. However, if all animals within a cluster are vaccinated, direct effects at the individual animal level cannot be estimated.

The choice of study design will depend on the programme’s objectives, funding, logistics and willingness of farmers to participate, which may justify adaptations.

For more detailed information on the considerations of RCTs used for estimating vaccine efficacy, please refer to [Chapter 11](#) in *Veterinary Epidemiologic Research* (Dohoo *et al.*, 2009).

Table 2. Description, requirements, advantages and limitations of different types of randomised controlled trial (RCT) designs that could be used for field evaluation of ASF vaccines

RCT	Description	Requirements	Advantages	Limitations
Individual randomisation	Pigs within the same group (e.g. pen, farm or village) receive either the candidate vaccine or a placebo (or a vaccine unrelated to the target disease). It may require more than one farm to achieve the desired sample size, in which case it becomes a multisite randomised controlled trial (MRCT).	<ul style="list-style-type: none"> • Detailed animal records. • Ability to randomise at animal level. • Logistics to ensure that vaccinators and farmers are blinded (i.e. unaware of the treatment group). 	<ul style="list-style-type: none"> • High internal validity. • Straightforward control of known confounders. • Ensures equal probability of exposure. • Useful when there is substantial heterogeneity in the baseline transmission across study sites. 	<ul style="list-style-type: none"> • May be impractical in the field (especially in some production systems, e.g. subsistence or backyard). • Risk of animals receiving the wrong treatment. • If MRCT is implemented, between-cluster variation needs to be considered, increasing the sample size. • May underestimate vaccine efficacy as only direct effects are considered.
Stratified randomisation	Pigs are separated into strata (i.e. groups) based on characteristics that may influence the outcome (e.g. production stage, production system, age, sex, etc.). Individuals within each stratum are randomly assigned to receive either the candidate vaccine or a placebo (or a vaccine unrelated to the target disease).	<ul style="list-style-type: none"> • Detailed animal records. • Ability to randomise at the animal level. • Individuals within strata must be epidemiologically homogeneous. • Prior knowledge of risk factors is likely to affect outcomes. 	<ul style="list-style-type: none"> • Balanced group sizes reduce bias and facilitate robust analysis by optimising statistical power, particularly in small sample sizes. • Suitable for large countries with large populations or geographically dispersed farms. • Ensures equal distribution of animals with specific characteristics across strata (groups). 	<ul style="list-style-type: none"> • Ensuring a similar level of exposure across strata may be challenging. • May underestimate vaccine efficacy, as only direct effects are considered.
Cluster randomisation	Farms (or pens) are separated into two or more groups (i.e. clusters), and all animals within each cluster receive either the candidate vaccine or the placebo (or vaccine unrelated to the target disease).	<ul style="list-style-type: none"> • Participation of multiple herds/farms. • Ability to randomise at the group level. • Detailed cluster-level data. • Individuals from different clusters cannot be mixed or be in close contact. 	<ul style="list-style-type: none"> • Simpler logistics for assigning vaccine and placebo. • Provides information on vaccine effects both at the individual and population levels (i.e. direct and indirect effects). 	<ul style="list-style-type: none"> • Requires larger sample sizes and more complex analysis than other study designs. • Risk of imbalance between treatment groups (e.g. important differences in the distribution of baseline characteristics that could be confounders), such as differences among farms (clusters) in management practices, which can be unevenly distributed. • Likelihood of exposure can vary over time.
Stepped wedge	All the farms (clusters) receive the candidate vaccine at different times (steps) during the study (i.e. there is no control group). The timing of the intervention is randomised.	<ul style="list-style-type: none"> • Sequential rollout. • Repeated measures. • All clusters (farms or villages) receive the vaccine. 	<ul style="list-style-type: none"> • Since there is no control group, this may enhance farmer acceptance by assuring vaccination for all the farms. • Efficient use of resources. 	<ul style="list-style-type: none"> • Complex design and analysis, requiring consideration of time-varying effects. • Limited use for vaccines in livestock, though applied in other veterinary interventions. • Likelihood of exposure may vary over time.

Note: When a new ASF vaccine becomes available in the future, a non-inferiority design could be used to compare it with an established vaccine instead of a placebo. Alternatively, a three-group (arm) study design comparing a new vaccine under investigation with both an established vaccine and a placebo control could be used. Guidance on the design of non-inferiority studies is available in the [Guideline on statistical principles for clinical trials for veterinary medicinal products \(pharmaceuticals\)](#) (EMA, 2012).

ii. Study site selection

The study site should be located in a geographical area where pigs are likely to be exposed to natural ASFV challenges, particularly in regions with a history of frequent outbreaks. It is essential to identify seasonal and disease patterns before planning the study timeline and to ensure that the virus strain(s) against which the vaccine candidate has been developed are circulating in the study area. Selection of an appropriate study site may be supported by seroprevalence studies or risk assessments to pinpoint high-risk areas. Conducting studies in high-risk, high-incidence areas can improve the efficiency of the study design.

To reduce variability and thus optimise study efficiency, farms included in the field study should be of the same production type (e.g. farrow-to-finish, farrow-to-wean, wean-to-finish, etc.) so that management practices and levels of biosecurity are comparable. To assess heterogeneity in vaccine efficacy between different pig production types or stages, either separate studies should be conducted for each category (see stratified randomisation in **Table 2**), or the study population size should be increased.

In addition, the study period should align with the duration of the pig production stages for which the candidate vaccine is intended (finishing pigs, sows, weaners, etc.), and the study site should allow for adequate follow-up of study animals.

iii. Ethical considerations

The implementation of randomised trials in field studies can help ensure representativeness and prevent uneven resource allocation among farmers. However, this approach implies that some animals and/or farms will not have access to a potentially beneficial intervention, which may be perceived as unfair. Such concerns should be addressed, and a compensation programme must be incorporated into the trial. It is critical to ensure transparency and to provide farmers with a protocol outlining how to manage outbreaks and/or any side effects/adverse reactions associated with the vaccine.

As part of the study site selection, sample size estimation, and prior to the selection of study units (e.g. pigs, pens, farms, villages), the following should be considered:

- It is important to consult farmers and industry stakeholders to determine a feasible number of animals that can be included in the study without disrupting production dynamics.
- Discussion must include mechanisms for compensation, especially in cases where the vaccine is not yet registered in the country. In such cases, pigs involved in the trial will need to be culled and will not be allowed to enter the food value chain; therefore, financial compensation for the value of the animals should be considered, and appropriate arrangements for carcass disposal should be in place.
- All participating farmers should provide verbal or written consent prior to recruitment and be fully informed about the use of either a vaccine or a placebo, for example through an information sheet in the appropriate language.
- Before the trial starts, ethical approval must be obtained from the relevant within-country review committees, as appropriate.
- For multinational or regional studies, the trial should also comply with international standards of Good Clinical Practice, as detailed in the [VICH GL9 international guidance document](#) (VICH, 2000).

- Measures should be taken to ensure that minimum pain and distress are caused to pigs participating in the study, and humane endpoints should be defined.
- Although the vaccine is not expected to cause severe adverse effects at this stage, less common side effects may occur; therefore, any changes in animal behaviour or physiology should be recorded.
- In the event of an outbreak at the study site, it is crucial to prevent the spread of the virus to other local farms. Predefined measures to minimise the spread of ASF outbreaks should be established before the start of the vaccination programme.

iv. Sample size

It is essential to ensure that the sample size is representative of the target population for which the study results will be used. For determining vaccine efficacy, the sample size depends on:

- the expected number of new cases (based on the case definition) of ASFV infection in unvaccinated animals;
- the expected number of new cases (based on the case definition) of ASFV infection in vaccinated animals;
- the expected vaccine efficacy;
- the level of significance;
- the statistical power (Carpenter, 2001) (See [Annex 1](#)).

The expected vaccine efficacy can be derived from *ex situ* trials conducted by the vaccine manufacturer. The expected number of new cases in vaccinated animals (ii) can be determined if the expected number of new cases in non-vaccinated animals (i) and vaccine efficacy (iii) are known.

Figure 4 illustrates how these parameters interact.

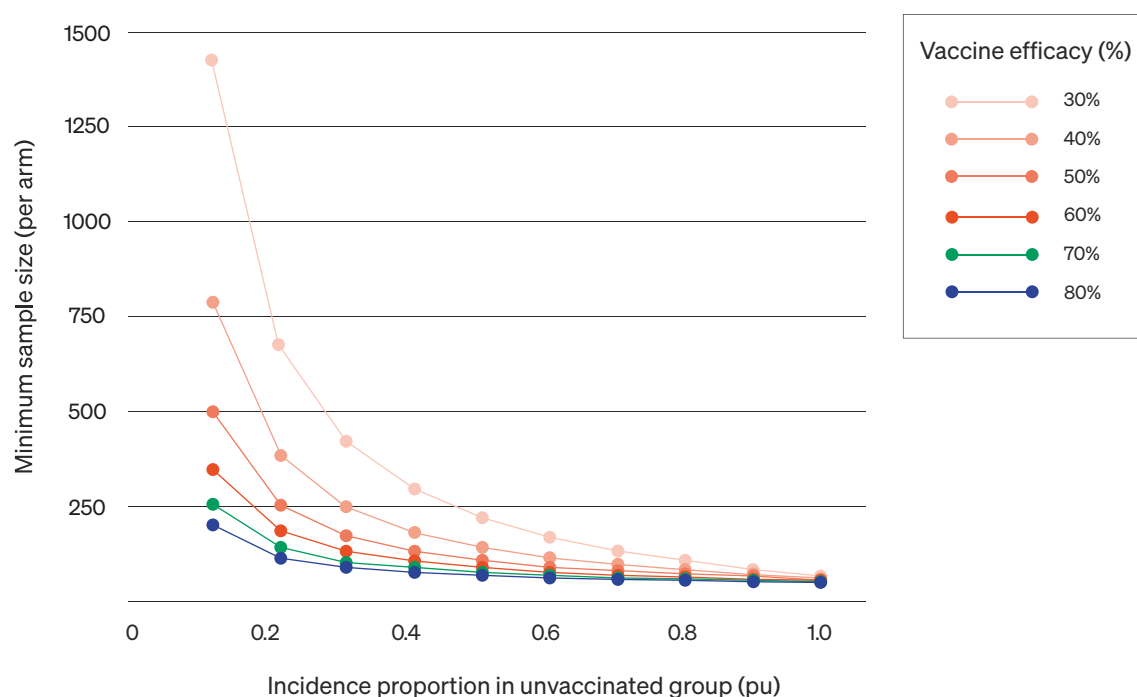


Figure 4. Minimum sample size (n) required per group based on the expected incidence proportion (pu) in the unvaccinated group and expected vaccine efficacy (%)

The following freely accessible online tools can be used to calculate sample size: Epitools (Ausvet, 2025) and [APCOVE](#) (2026).

Note : The sample size should be increased (corrected) to account for the following:

- (i) The expected proportion of animals being ASF seropositive at the start of the study, which would be excluded (see inclusion and exclusion criteria);
- (ii) Potential exposure within 14 days post-vaccination (the assumed onset of immunity post-vaccination);
- (iii) The proportion of animals expected to be lost to follow-up (e.g. death);
- (iv) The level of clustering within the unit of analysis (e.g. village, farm, pen), i.e. the degree of similarity among pigs within the unit.

Selection of an appropriate sample size also involves non-statistical factors, such as available resources (e.g. time, money), sampling frames, and the objectives of the vaccination programme. Efforts should be made to maximise sample size while taking into account logistical challenges and the local context.

v. Inclusion and exclusion criteria

Reasons for inclusion and exclusion of animals or farms should be clearly defined in the study protocol.

Inclusion criteria may include, but are not limited to:

- (i) Pigs must be seronegative at the beginning of the study (Day 0);
- (ii) The age and production stage of pigs must follow the manufacturer's recommendations for the vaccine under evaluation;
- (iii) Availability of good record-keeping systems or willingness to record data systematically during the study.

Exclusion criteria may include, but are not limited to:

- (i) Any history of ASF in the animal or on the farm of origin (based on historical records and/or clinical examination) within a specified timeframe; the duration of this period will depend on the production cycle;
- (ii) Previous vaccinations against ASF or evidence of prior exposure to ASFV (i.e. presence of ASFV antibodies) in an individual animal;
- (iii) Presence of any other illness or disease at enrolment (based on animal records or clinical examination) in individual pigs.

vi. Randomisation

In study designs where pigs are the unit of randomisation, pigs within each participating unit (e.g. farm or pen) should be assigned to either the vaccine group or the control group. Including pigs from both groups within the same unit and maintaining them under comparable conditions helps ensure a consistent level of exposure for both vaccinated and non-vaccinated animals.

Before recruitment begins, a randomisation table should be prepared by a team member who is not involved in the vaccination or follow-up process (**Example 1**). This table will guide the vaccinator in administering vaccines according to the assigned sequence. Each group should be assigned a specific identification (e.g. ear tag numbers) corresponding to vials containing either the candidate vaccine or the placebo control (**Example 2**). Similarly, when randomisation is conducted at the farm level (i.e. cluster randomisation), farms should be pre-assigned to either the vaccine or placebo/control group.

The following examples illustrate how randomisation schedules and vial labelling can be implemented in practice :

Example 1. Variable block randomisation to ensure a balanced allocation of treatment groups. Adapted from Lyons *et al.* (2019)

Farm	Animal									
	1	2	3	4	5	6	7	8	9	10
1	A	B	B	A	A	B	A	B	B	A
2	B	A	B	A	A	A	B	A	B	B
3	B	A	A	B	A	B				
4	A	B	A	B						

A = vaccine candidate; B = placebo

Example 2. Example of vial labelling and dose allocation based on the randomisation schedule. Adapted from Limon *et al.* (2025)

Farm	Animal	Doses (number of animals)	Code on the vial
Farm 1	1	5	A
	2	5	B
	3	5	A
	4	5	B
Farm 2	1	5	A
	2	5	B
	3	5	A
	4	5	B

A = vaccine candidate; B = placebo

vii. Blinding

Ideally, all the personnel involved in the study (including vaccinators, veterinarians, farmers, laboratory staff and data analysts) should be 'blinded' to the treatment groups to prevent the introduction of bias. This means that both the candidate vaccine and the placebo must be visually identical and differentiated only by a code, which should be generated and stored by a designated team member who is not directly involved in the trial.

In cases where 'blinding' is not possible, at a minimum, farmers should be blinded to ensure that animals are not treated differently.

viii. Vaccination protocol and sampling

Baseline visit

A survey of the farm(s) should be conducted using a standardised questionnaire (preferably in digital format) to collect:

- Farm level data: number of animals, management practices, biosecurity measures, previous ASF outbreaks on the farm and history of other diseases.
- Animal-level data (for all animals included in the study): unique ID, age, sex, origin, breed, relevant health status, vaccination history and current or recent medicines administered.

Vaccination and sampling

The recommended protocol for vaccination and sampling is as follows (see **Figure 5**):

- Prior to vaccination (or placebo administration), blood samples should be collected using pre-labelled serum vacutainers to establish baseline values for each pig included in the study. Ideally, these samples should be collected a few days before Day 0, allowing time to determine ASF serostatus and eligibility of pigs for inclusion in the study.
- Day 0: administration of a single dose of the candidate vaccine or placebo. All pigs should be observed for at least 15 minutes following vaccination/placebo administration to record any side effects.
- Day 0, 7, 14, 21, 28, 60, 120 and, if possible, 240 days post-vaccination (dpv) :
 - Rectal, oral and nasal swabs collected in an appropriate viral transport medium, or collected dry (depending on laboratory preference)
 - Blood samples: ethylenediaminetetraacetic acid (EDTA)-blood (purple caps) and serum (red or gold caps)
- Post-mortem examinations should be conducted for any pigs that die on the farm (for any reason) throughout the study period. EDTA-blood, serum (if possible) and tissue samples (ideally spleen, lymph nodes, bone marrow, lung, tonsil and kidney) should be collected in an appropriate viral transport medium.

Note: It is recommended that all sample types be collected from each animal. However, this may not be logistically or ethically feasible, and in such cases, consistency in sample type should be maintained throughout the study. Oral swabs are recommended over nasal swabs, as these have been shown to be more sensitive for detecting virus shedding following vaccination and challenge (Vreman *et al.*, 2025) and are also less invasive for pigs. However, nasal swabs may be easier to collect under certain field conditions.

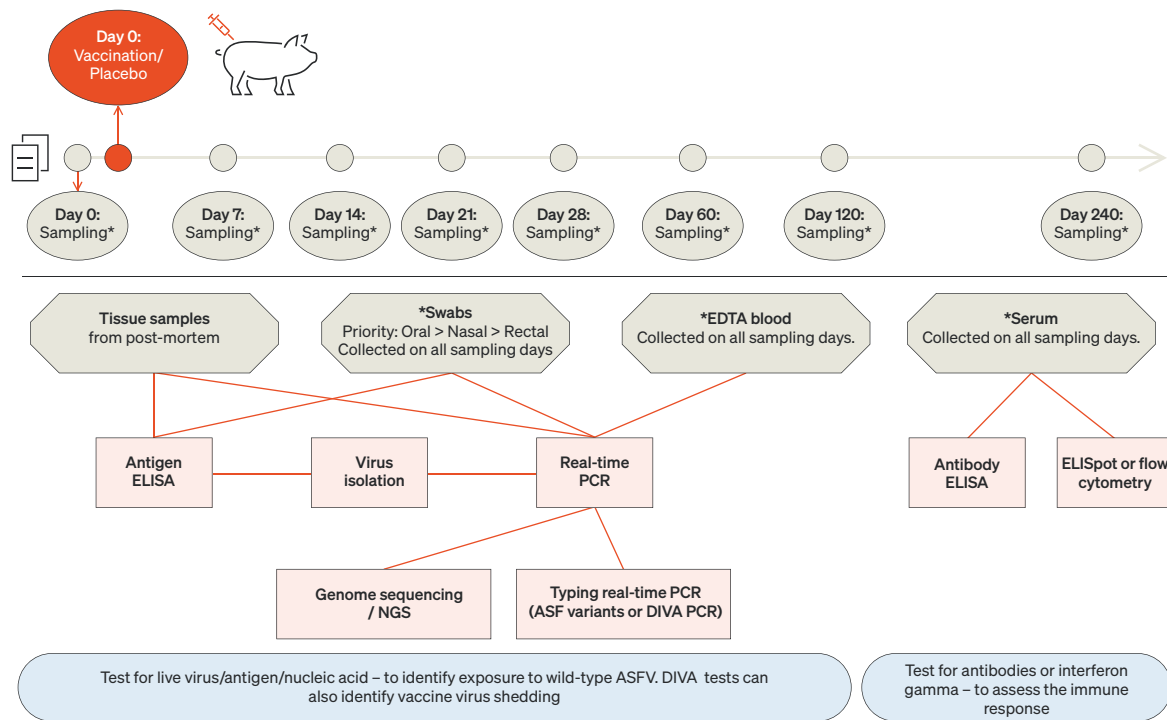


Figure 5. Sampling and testing protocol for vaccine efficacy studies in the field

Swabs, EDTA blood and serum should be collected on all sampling days, while tissues should be collected at post-mortem from any pigs that die on the farm. It is also recommended that serum samples are collected prior to Day 0 to determine the serostatus and therefore eligibility of pigs for the study.

ASF – African swine fever; ASFV – African swine fever virus; DIVA – Differentiating infected from vaccinated animals; EDTA – Ethylenediaminetetraacetic acid; ELISA – Enzyme-linked immunosorbent assay; ELISpot – Enzyme-linked immunospot assay; NGS – Next-generation sequencing; PCR – Polymerase chain reaction

Logistical considerations

- Pre-loaded vaccine syringes should be labelled to match the randomisation table. If this is not feasible, the vaccinator should use vials with plain labelling, and vial numbers should be cross-referenced with the randomisation table. The vial or syringe number should be recorded alongside the unique animal ID number.
- The vaccine and placebo must be administered via the same route (e.g. intramuscularly) and at the same volume.
- Blood samples, and rectal, oral and nasal swabs should be collected as quickly and aseptically as possible, ensuring minimum stress to the animal.
- Samples should be collected by a veterinarian or trained personnel, using pre-labelled tubes to avoid typing errors and sample mix-ups.
- Blood samples should be collected and handled with care to avoid haemolysis.
- Field sample storage and transport of samples to the laboratory should be carefully planned, including maintenance of a cold chain. The quality of sample collection and storage should be considered, as it may affect test results.

ix. Data collection

Data to be collected throughout the study using a standardised recording sheet include, but are not limited to:

- Animal temperature: temperature data loggers can be used to facilitate logistics and reduce animal stress.
- Any unusual signs of ill health: the case definition can be used to help determine whether these are likely due to ASFV.
- Record of ASFV outbreaks occurring on farm or in the surrounding area during the study period.
- Animal-level data on any updates to preventive medicine administered during the study (e.g. deworming, tick control).
- Any other relevant data, depending on the predefined outcomes of interest.

Note: A standardised recording sheet should be provided to farmers to facilitate consistent data collection of the above information (see the template in [Annex 2](#)). In addition, data should be collected by a veterinarian or trained personnel at Day 0 and at each subsequent sampling point, using either a paper form or electronic formats. Any errors or challenges encountered during the study should also be documented.

x. Sample testing

Validated laboratory methods should be used, as described in the *Terrestrial Manual Chapter 3.9.1*. 'African Swine Fever (Infection with African Swine Fever Virus)' (WOAH, 2025a) and [Addressing African Swine Fever: Guidelines for Laboratory Diagnosis](#) (WOAH, 2024).

To assess the immune response:

- Serum samples should be tested to assess the humoral response (IgG) using ELISA (commercial kits or in-house assays).
- Where feasible (depending on sample transport time), blood samples should be tested for interferon gamma (IFN- γ) using assays such as ELISpot or flow cytometry to assess the T-cell response.

To identify exposure to wild type ASFV:

- EDTA-blood, serum and rectal, oral and nasal swabs, as well as any post-mortem tissue samples, should be tested for ASFV DNA by real-time PCR.
- A typing real-time PCR (e.g. ASFV variant or DIVA PCR) should be performed on positive PCR samples to differentiate wild-type virus from variants or vaccine viruses. The choice of test requires knowledge of circulating wild-type ASFV strains and any other vaccines used in the region.
- Sequencing (e.g. partial genome or Next Generation sequencing) should be performed on selected PCR-positive samples, where possible, to obtain further characterisation and identify potential recombination events.
- Virus isolation may be performed on PCR-positive samples (if the collection method does not include a DNA preservative) where virus propagation is required for further characterisation.
- Antigen ELISA may also be used as a differential diagnostic method where other techniques are not available.

3.4 Statistical analyses

Before starting statistical analyses, the approach used to analyse the treatment received (vaccine or placebo) should be defined (intention-to-treat versus per-protocol analysis).

The most common approach used for estimating vaccine efficacy is the relative reduction in incidence between vaccinated and unvaccinated animals:

$$\text{Vaccine efficacy} = \left(1 - \frac{\text{Incidence risk}_{\text{vaccinated}}}{\text{Incidence risk}_{\text{unvaccinated}}}\right) \times 100$$

The incidence, or number of new cases, should be defined according to the case definition and outcome measures specified in advance. **Example 3** illustrates how vaccine efficacy can be calculated using this approach

Example 3

Outcome of interest: reduction in clinical signs.

Of 100 vaccinated pigs, 10 showed clinical signs. Of 100 pigs that received a placebo, 70 showed clinical signs. Therefore, the incidence of clinical signs in the vaccinated group is 0.1, and the incidence in the placebo group is 0.7. Vaccine efficacy can be estimated as follows:

$$\begin{aligned}\text{Vaccine efficacy} &= \left(1 - \frac{0.1}{0.7}\right) \times 100 \\ &= (1 - 0.143) \times 100 \\ &= 0.857 \times 100 \\ &= 85.7\%\end{aligned}$$

For analyses of vaccine efficacy based on time-to-event outcomes, Cox proportional hazards regression models should be used. In this case, vaccine efficacy is estimated as the relative reduction in the outcome between vaccinated pigs and pigs receiving the placebo.

$$\text{Vaccine efficacy} = \left(1 - \frac{\text{Events}_{\text{vaccinated}}/\text{animal time}}{\text{Events}_{\text{unvaccinated}}/\text{animal time}}\right) \times 100$$

OR

$$\text{Vaccine efficacy} = (1 - \text{hazard ratio}) \times 100$$

Here, *Events* corresponds to new cases based on the case definition (incidence rate) in each group during the study period. Since *animal time* represents the number of individuals per unit of time, this unit (e.g. days or weeks) must be clearly defined and used consistently throughout the whole study. This approach assumes that the relative risk of the event, and therefore the estimated vaccine efficacy, remains constant over time.

Example 4 illustrates how vaccine efficacy can be calculated while accounting for the time animals are followed up in each group

Example 4

Outcome of interest: reduction in clinical signs.

Using the previous example, and assuming groups were observed for 24 weeks (vaccinated) and 25 weeks (placebo), and no animals were lost in follow-up, we can conclude that each group had contributed to $(100 \times 24 =) 2,400$ and $(100 \times 25 =) 2,500$ animal/week (or 16,800 and 17,500 animal/day, respectively). Vaccine efficacy can then be estimated as follows:

$$\begin{aligned}\text{Vaccine efficacy (VE)} &= \left(1 - \frac{(10/2400)}{(70/2500)}\right) \times 100 \\ &= (1 - (0.004/0.028)) \times 100 \\ &= (1 - 0.149) \times 100 \\ &= 0.851 \times 100 \\ &= 85.1\%\end{aligned}$$

Note: This example illustrates where there may be variation in the number of weeks each group was followed. Although equal follow-up time for each group is preferable, this may be difficult to achieve under field conditions. Such variations should not affect the VE estimation, provided the sample size and analysis are adequate.

Further analysis and important considerations

The analyses described above are crude and do not account for other potential factors such as clustering of animals within farms, different points of entry, etc. Even with randomisation, groups may not be fully balanced with respect to all potential confounders or variation between farms. To account for these potential confounder variables, multivariable logistic regression models or multivariable Cox proportional hazards regression models (for time-to-event outcomes) should be used. If multiple farms are included in the RCT, farm should be included as a random effect to control for the effect of clustering within farms.

For more complex analytical approaches, see Dohoo *et al.* (2009) or Halloran *et al.* (2009).

4. Benefit–risk assessment prior to the launch of a national or regional vaccination programme

Although vaccination is generally beneficial for disease reduction, it may also involve several risks. Therefore, following vaccine efficacy trials in the field, and before launching a national vaccination programme, each country or region should conduct an initial benefit–risk assessment to evaluate the potential positive effects (i.e. benefits) of the vaccine in relation to the associated risks.

The assessment should consider the local context, production system(s) and production stage in which the vaccination programme will be rolled out, as well as the country’s aims and priorities for ASF control (e.g. reducing the number of ASF outbreaks, lowering mortality, reducing transmission or recovering disease-free status and access to trade, etc.). For this purpose, results and experiences from field RCTs (see **Section 3**), together with data provided by the vaccine manufacturer, should be used to assess the direct benefits and risks of the proposed programme. Additional benefits, such as economic factors, logistics for vaccine delivery, or the ability to differentiate infected from vaccinated animals (DIVA), should not be included in this initial benefit–risk assessment but may be considered in a subsequent, comprehensive benefit–risk evaluation. It is important to involve all stakeholders in this process to ensure a rounded overview of benefits and risks across the value chain. **Figure 6** provides examples of potential benefits and risks associated with the use of vaccines for the prevention and control of ASF. These examples are not exhaustive, and may vary depending on the vaccine, production system and objectives of the vaccination programme. Where applicable, existing guidance on the evaluation of the benefit–risk balance of veterinary medicinal products, such as the EMA (2024) [Guideline on the evaluation of the benefit-risk balance of veterinary medicinal products](#), should be considered.

If the results of the RCTs do not demonstrate good vaccine performance, the country should carefully consider whether authorisation or deployment of the vaccine is justified and ethical. In such cases, additional vaccine efficacy trials may need to be performed, followed by further benefit–risk assessments, before rollout of a national vaccination programme. Where a decision is made to proceed with the vaccination programme, appropriate mitigation measures should be developed for the identified risks.

A comprehensive overall assessment of the benefit–risk balance should also be conducted once data from a post-vaccination monitoring and evaluation programme are collected and analysed (see **Section 5**). This broader evaluation should consider all aspects of decision-making, including financial, logistic, technical and geopolitical factors.

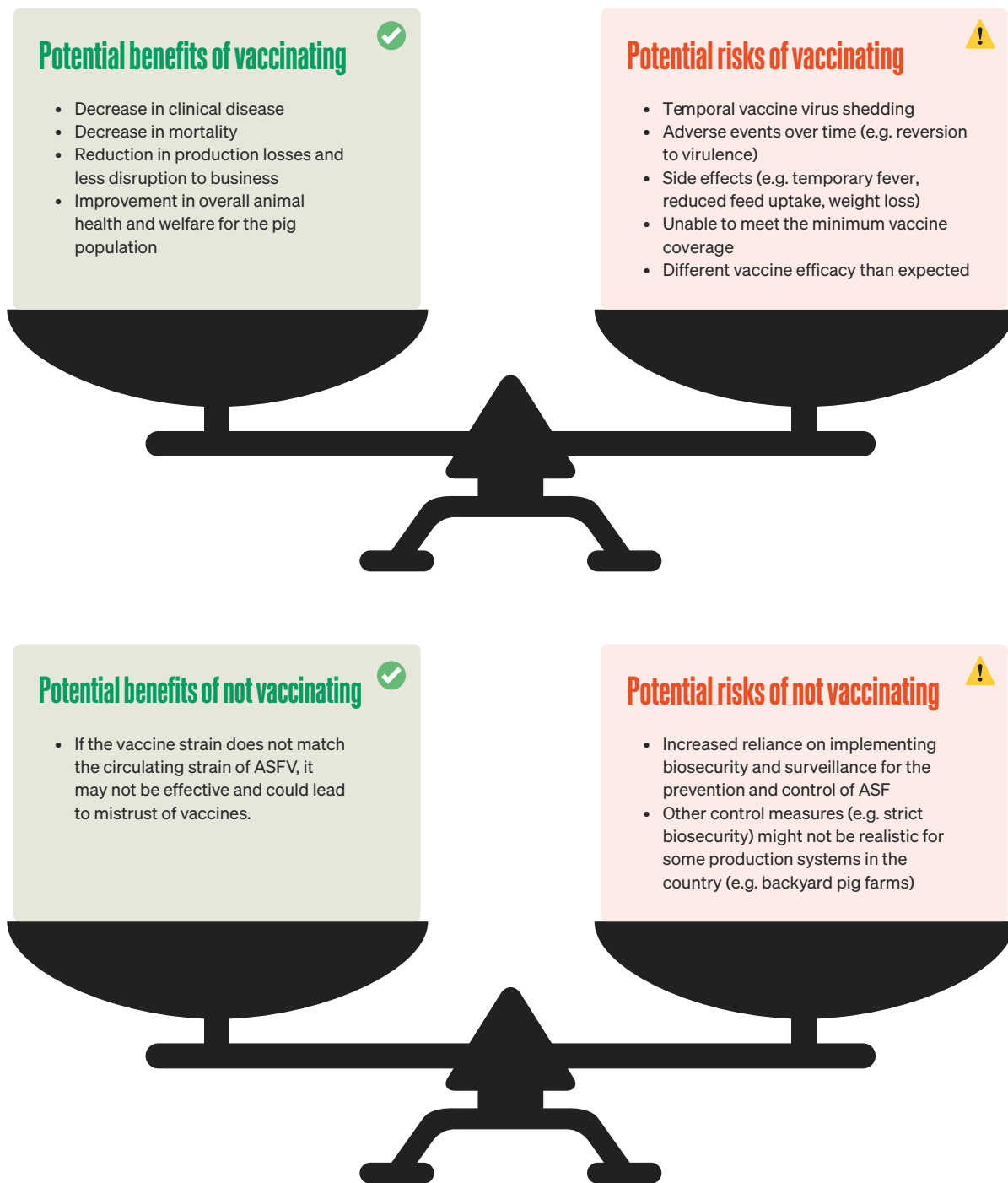


Figure 6. An example of the potential risks and benefits associated with ASFV vaccination

This figure is for illustrative purposes only and does not represent an exhaustive list. Risks and benefits may vary depending on local contexts.

5. Field monitoring following implementation of an ASF vaccination programme

This section outlines the essential requirements and tools for developing an effective and sustainable strategy for monitoring the ASF vaccination programme post-rollout. Where feasible, gradual rollout to the target population should be considered as confidence develops under local conditions.

It is important to keep in mind that ASF vaccination should be considered as one of several tools for ASF prevention and control, and should be integrated within a comprehensive prevention and control programme that may incorporate measures such as compartmentalisation (see WOA's [Compartmentalisation Guidelines – African Swine Fever](#) [OIE, 2021]), movement restrictions, and biosecurity improvements. Therefore, the post-vaccination monitoring programme should align with the objectives defined in **Section 3.2** (Outcome measures).

5.1 Post-vaccination monitoring and evaluation of vaccine effectiveness

In contrast to vaccine efficacy studies, which assess how well a vaccine protects against ASF under conditions recommended by the manufacturer, vaccine effectiveness studies evaluate performance in real-world settings, with or without an official vaccination programme, and can assess the vaccination programme as a whole (Knight-Jones *et al.*, 2014). Evaluation of vaccine effectiveness should involve both Veterinary Services and Veterinary Authorities, supported by an independent advisory committee without conflicts of interest in vaccine production or distribution.

i. Study design

The study design for vaccine effectiveness evaluation must align with the national ASF vaccination objectives and policy frameworks for ASF prevention and control. Observational studies, such as case-control and cohort studies, are most commonly used. Design considerations include, but are not limited to:

- (i) production systems (e.g. commercial or subsistence-use systems);
- (ii) production stages (e.g. finishing pigs, reproductive pigs or piglets);
- (iii) clinical disease;
- (iv) the prevalence of the circulating ASFV genotypes;
- (v) vaccine coverage.

Observational studies can present logistical challenges, as they require adequate funding and rigorous implementation to ensure valid and generalisable results; therefore, they may not be feasible in resource-limited settings. As a minimum, surveillance data based on passive reporting should be used to identify ASF outbreaks and compare new cases of ASFV infection between vaccinated and unvaccinated herds or farms.

For more information on study design considerations, including case definition, selection of the study population, sample collection and sample size calculation, please refer to **Section 3** of these guidelines and Chapter 7, 'Introduction to Observational Studies' in Veterinary Epidemiologic Research (Dohoo *et al.*, 2009).

Table 3 outlines key characteristics of case-control and cohort studies for assessing vaccine effectiveness.

Characteristics	Observational study	
	Case-control	Cohort
Description	Compares the odds of vaccination in individual pigs or herds that developed the outcome of interest (cases) <i>versus</i> those that did not (controls) during an outbreak. The number of individuals at risk in vaccinated and unvaccinated groups is not directly observed; instead, controls are used to estimate the distribution of vaccination in the population that gives rise to the cases. Therefore, controls should be chosen independently of their vaccine status.	Follows vaccinated and unvaccinated pigs (or herds) over time, comparing disease incidence. Types: <ul style="list-style-type: none"> • Prospective: pigs are followed forward from vaccination. If all vaccinations occur before the observation period, this constitutes a fixed cohort. • Retrospective: based on historical data (e.g. outbreak records).
Strengths	Suitable when the disease is rare or under control. Requires fewer animals than a cohort study. Relatively shorter time to complete and lower cost than cohort study.	Direct incidence measurement. Allows assessment of multiple outcomes. Can account for time since vaccination and establish temporal sequence (or temporality of association) between exposure and outcome. Enables collection of detailed information on potential confounders.
Limitations	Difficult to establish temporality of association. Risk of selection bias (choice of controls). Limited availability of unvaccinated animals when vaccine coverage is high. Requires reliable vaccination history. Potential recall bias if information is based on farmer reports.	Requires large populations and follow-up (hence longer study period and higher cost). Issues related to loss of follow-up. Risk of confounding if not addressed in study design.
Sample size	Case-control for 1:1 matching (can be adjusted for different ratios, e.g. 1:2). Best if case-to-control ratio is 1:4. Information needed: <ul style="list-style-type: none"> • Exposure prevalence among controls • Exposure prevalence among cases • Confidence level 	Sample size to compare two proportions. Information needed: <ul style="list-style-type: none"> • Event risk in unvaccinated group • Event risk in vaccinated group • Confidence level • Statistical power
Vaccine effectiveness estimation	$VE = (1 - OR) \times 100\%$ Where OR is the odds ratio of vaccination among cases <i>versus</i> controls.	$VE = (1 - RR) \times 100\%$ Where RR is the relative risk of disease in vaccinated <i>versus</i> unvaccinated groups
Case-control and cohort studies are the most commonly used designs. A case-control study can be considered a sample drawn from a (hypothetical) cohort study, in which cases and controls are selected based on the presence or absence of the outcome of interest. The cohort represents the source population from which the cases arise.		

ii. Outcome measures

The study outcomes should align with the aim of the vaccination programme within the broader context of the country's national or regional ASF control programme (see examples in [Table 4](#)). As stated in [Section 3.2](#), it is important to define the outcome measures and case definitions clearly in advance, as these may vary between regions and production systems. It is also important to recognise that, once the vaccination programme begins, the transmission dynamics of ASFV within the population are likely to change over time.

Several factors should therefore be considered, as they strongly influence the outcomes:

- The baseline level of transmission of ASFV within the target population, which will evolve over time as the vaccination programme and accompanying ASF control measures are implemented.
- The expected effectiveness of the vaccine.
- The vaccine coverage (i.e. percentage of the population to be vaccinated) when planning the vaccination strategy.

For further information on the design considerations of vaccine effectiveness studies (e.g. selecting the study population, determining the minimum sample size, defining and identifying cases, collecting samples, and conducting statistical estimation and inference), please refer to [Section 3](#) in these guidelines and to [Chapter 7, 'Introduction to Observational Studies'](#) in *Veterinary Epidemiologic Research* (Dohoo et al., 2009).

Table 4. Examples of outcome measures for differing control programme goals (non-exhaustive list)

Aim of the control programme	Potential outcomes measures
Reduction in the number of ASF outbreaks in the country	<ul style="list-style-type: none">• Reduction in the incidence of ASF outbreaks
Minimise the impact of ASF outbreaks (e.g. reduction of severity and infectiousness)	<ul style="list-style-type: none">• Reduction in mortality• Reduction in the severity of clinical signs• Reduction in transmissibility
Prevention of ASFV spread or establishment in the country	<ul style="list-style-type: none">• Reduction in transmissibility• Reduction in mortality
Eradication in the country and return to disease-free status.	<ul style="list-style-type: none">• Reduction in transmissibility

iii. Sampling and laboratory testing

Samples should be collected for surveillance, including serological evaluation, to identify exposure to ASFV and to detect potential reversion to virulence or recombination events. This can include the collection of serum samples, EDTA blood, rectal, nasal or oral swabs, and tissue samples from animals submitted for post-mortem, alongside data on clinical signs and potential side-effects (see [Section 5.2](#)).

As outlined in [Section 3.3](#), it is recommended to use validated laboratory methods, as described in the *Terrestrial Manual Chapter 3.9.1. 'African Swine Fever (Infection with African Swine Fever Virus)'* (WOAH, 2025a) and [Addressing African Swine Fever: Guidelines for Laboratory Diagnosis](#) (WOAH, 2024).

The collation of post-vaccination monitoring laboratory results, combined with epidemiological data, may help determine correlates of protection for ASF vaccines and support differentiation between vaccinated and infected animals or herds.

5.2 Post-vaccination monitoring of side effects (pharmacovigilance)

Pharmacovigilance and the ongoing monitoring of vaccinated pig populations are crucial for assessing vaccine effectiveness, maintaining programme confidence and identifying side effects or adverse events post-vaccination.

i. Identification of side effects following vaccination

Monitoring post-vaccination side effects is a shared responsibility among vaccine producers, policy-makers, Veterinary Authorities and farmers throughout vaccine deployment. **Figure 7** provides a schematic framework of the recommended three-step monitoring process, including key requirements, considerations and challenges. A detailed explanation of each step is provided below. This section should be read in conjunction with [How to set up a pharmacovigilance system for veterinary medicinal products](#) (WOAH, 2022).

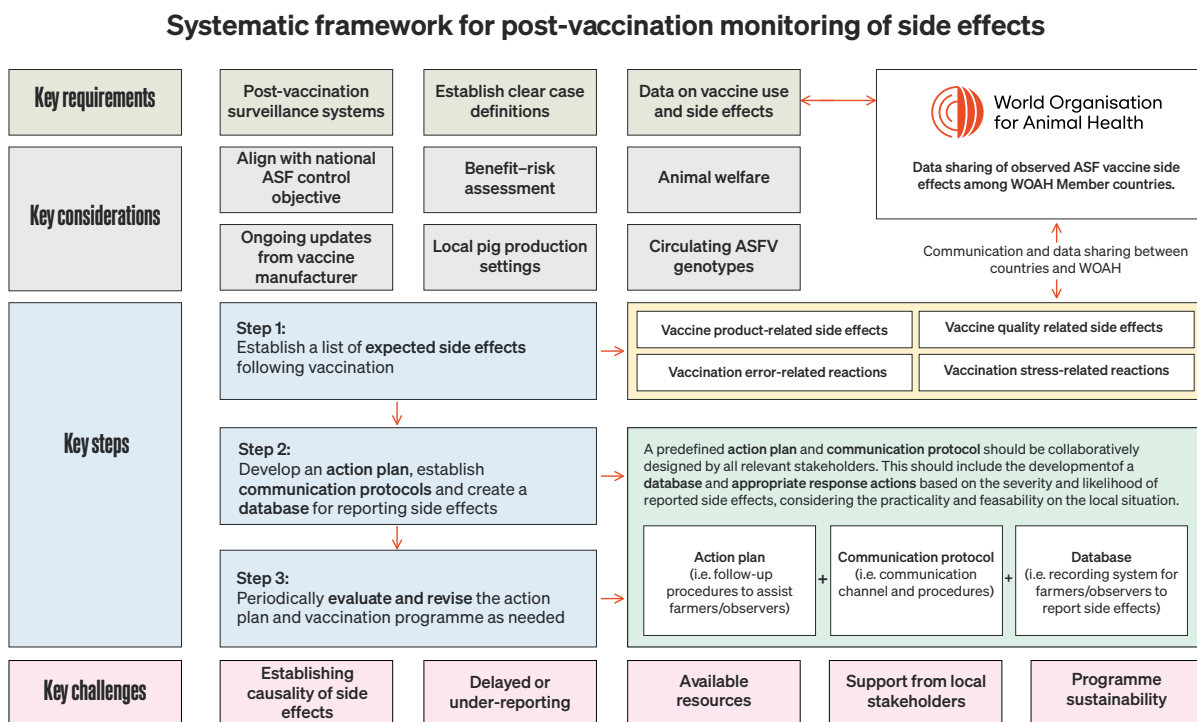


Figure 7. A schematic framework of the suggested three-step process for monitoring side effects post-vaccination, including key requirements, considerations and challenges

These steps should not be considered prescriptive and should be adapted as needed, based on the objective of the ASF prevention and control programme and the unique local context

ii. Key requirements and considerations

A surveillance system is essential for the timely detection and reporting of post-vaccination side effects. Its objectives should be clearly defined and aligned with the country's ASF vaccination programme. Caution is required when potential side effects are identified, as the occurrence of an event following vaccination does not necessarily indicate it was caused by the vaccine.

When planning a surveillance system, in addition to the provisions described in the *Terrestrial Code* Chapter 1.4 (WOAH, 2025e), the following factors should be considered:

- The intended target population, and the feasibility of sampling it
- Data requirements (data sources, processing and analysis)
- Desired levels of surveillance performance (e.g. sensitivity, timeliness)
- Available resources (financial resources, personnel and laboratory capacities)
- Governance structure and regulatory framework
- Issues related to underreporting and delayed reporting

Additional guidance on surveillance types and methods can be found in the [Guide to Terrestrial Animal Health Surveillance](#) (OIE, 2014). Once surveillance methods are selected, clear case definitions should be established and periodically revised based on changes in programme objectives, the local situation, diagnostic advancements, circulating ASFV genotypes and evolving knowledge of the disease.

iii. Suggested steps for post-vaccination monitoring of side effects

Step 1 – Establish a list of expected side effects following vaccination

Based on product information from vaccine manufacturers (derived from the results of *in vivo* experimental studies), a list of expected side effects should be provided to farmers and Veterinary Services, together with appropriate reporting methods and response actions. This will help build trust and prevent misinformation regarding vaccine performance. Field data from other countries using ASFV vaccines should also inform these expected side effects. It is strongly recommended that Veterinary Services and Veterinary Authorities establish databases to collate and share observed side effects with WOA, thereby supporting global ASFV control efforts. Ideally, a shared global database, jointly maintained by WOA and national veterinary authorities, would provide a platform for countries to report observed side effects. Such a resource would expand over time and serve as a valuable repository accessible to WOA Members.

Box 1 provides a list of the most common types of side effects that may occur following vaccination. Reactions specific to ASF vaccines can include lethargy, fever, weight loss and disease in immunodeficient pigs (particularly when using LAV vaccines), among others.

Box 1. Summary of the most common side effects associated with vaccinations

(Adapted from [Causality assessment of an adverse event following immunization](#) [WHO, 2019])

Vaccine product-related reaction

Reactions associated with the route and/or site of administration of the vaccine product or vaccine-specific characteristics:

- a. Immune-mediated vaccine reactions:
 - I. Local reaction involving the injection site, due to one or more vaccine components.
 - II. Multisystem (generalised) reaction due to one or more vaccine components.
 - III. Organ-specific reaction due to one or more vaccine components.

Vaccine quality defect-related reaction

- b. Reactions due to replication of vaccine-associated microbial agent(s) in the vaccinee or in close contacts. The microbial agent(s) could be:
 - I. An attenuated vaccine agent.
 - II. A wild-type vaccine agent due to insufficient inactivation during the manufacturing process.
 - III. A contaminant introduced into the vaccine during the manufacturing process.

Vaccination error-related reaction

- c. Errors in vaccine handling (e.g. exposure to excessive heat or cold due to inappropriate transport, storage or handling).
- d. Errors in vaccine prescribing or administration, or non-adherence to recommended use.

Vaccination stress-related reaction

- e. Stress-related responses to vaccination can be triggered and may manifest just prior to, during or after vaccination. Discomfort can arise due to both the restraints required and the inoculation itself involved in the vaccination process.

Step 2 – Establish an action plan, communication protocol and database for recording side effects

Farmers with vaccinated herds should be advised to remain vigilant, monitor for signs of illness in the herd and report any side effects to the Veterinary Authorities.

Based on the likelihood and severity of expected side effects, a predefined action plan and communication protocol should be established. Appropriate communication channels should be in place to enable timely investigation and response.

Minimum information to be collected

The minimum required data should be clearly defined and collected systematically using standardised questionnaires as part of the investigation. These data can be collated in a database, allowing information on authorised vaccines and observed side effects to be analysed and shared with WOA. H.

To facilitate data collection, a predefined monitoring form can be provided to owners of vaccinated herds and Veterinary Services (e.g. an adapted version of the form in **Annex 2** for expected side effects). The specific information required will depend on the side effect detected, and some cases may warrant further investigation (e.g. qPCR testing and sequencing to assess potential reversion to virulence) in such cases, blood and oral swab samples should be collected from affected animals, as well as a subset of healthy vaccinated animals. For more information on appropriate diagnostic methods and approaches for detecting virulent and variant forms of ASFV, including potential mutation associated with the use of authorised live attenuated vaccines, please refer to [Addressing African Swine Fever: Guidelines for Laboratory Diagnosis](#) (WOAH, 2024).

Step 3 – Periodically evaluate the action plan and vaccination programme

Programmes for monitoring vaccine side effects should be routinely evaluated to ensure that they meet the defined objectives and identify areas for improvement. Evaluation activities should be prioritised and adequately resourced, and should be systematic, transparent and reproducible by qualified assessors. The evaluation process should focus on developing practical solutions, including actionable plans based on findings and guidance to improve overall programme effectiveness.

iv. Reversion to virulence and recombination

Reversion to virulence and recombination within and between genotypes are two major concerns when using live-attenuated ASFV vaccines, as these events may directly undermine vaccination and control efforts. A surveillance strategy should therefore be established to monitor circulating strains and detect any genetic drift following implementation of a vaccination programme.

Farmers should be encouraged to report outbreaks and any suspected side effects or adverse events, and a system should be in place to investigate these promptly. Monitoring outbreaks, as well as changes in disease virulence and clinical presentation using genomic surveillance approaches, is essential for the timely detection of mutations and shifts in virulence. Whole genome sequencing remains the recommended diagnostic technique for confirming reversion to virulence and virus recombination, despite associated cost or time constraints. Once the potential for reversion to virulence or recombination has been observed and reported, investigations should be initiated to collect clinical information and obtain blood samples for sequencing.

6. Knowledge gaps affecting vaccine evaluation studies

At the time of drafting these guidelines, vaccine design and development remain at an early stage, and knowledge is therefore limited. The following key gaps were identified during the preparation of these guidelines and may affect the assessment of vaccination programmes. It is strongly recommended that this document be reviewed annually to incorporate new evidence on the virus and its epidemiology.

Immune (humoral and cellular) response

Although all vaccines induce an immune response, correlates of protection have not yet been established for ASFV, and measurement of protection based on immune response alone is not yet reliable. In addition, cellular immune responses are difficult to assess under field conditions due to logistical constraints, including the short time between sampling and laboratory processing, and the labour-intensive nature of testing. As a result, assessment of vaccine performance is challenging when relying on crude outcome measures such as clinical signs. Nevertheless, humoral and cellular responses should still be measured where possible, as emerging patterns in the data may be informative in the future.

Survival and reduction of clinical signs after exposure

Although morbidity and mortality are generally considered the most reliable indicators of vaccine efficacy in the field, natural exposure to ASFV might vary in space, time and dose. A reduction in mortality and clinical signs does not necessarily indicate protection against ASF (due to a lack of sterilising immunity), but rather a reduction in disease impact. Furthermore, as vaccination programmes progress and herd immunity develops, ASF disease dynamics are expected to change, potentially altering the most reliable indicators for vaccine effectiveness. Without clearly defined correlates between the (humoral) immune response and protection, assessing the level of protection remains challenging.

Differentiating infected from vaccinated animals (DIVA)

Some live attenuated vaccines generated by targeted gene deletion, and sub-unit vaccine candidates can be differentiated from natural wild-type strains, for example, by qPCR or sequencing. However, at the time of writing, there are currently no standardised tests that can be used to differentiate between vaccinated and infected animals in the population. A reliable and high-throughput DIVA test (PCR or serology) would be essential if the aim of the vaccination programme is eradication.

Genomics

Whole genome sequencing, combined with parallel monitoring of herds for clinical disease, is a key tool for detecting reversion to virulence and recombination. However, the cost of whole genome sequencing remains a barrier for many countries, particularly given the number of samples that may need to be analysed during outbreaks.

Wild pigs and vectors

Contact between vaccinated domestic pigs and wild hosts might increase the risk of reversion to virulence of ASF LAV. It is important for countries to perform wildlife and vector surveillance where possible, to improve understanding of circulating strains and to detect reversion to virulence or recombination events.

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Annex 1. Sample size calculation

Multisite randomised controlled trial

Using the equation provided by Carpenter (2001), the sample size calculation (for each group) will be as follows:

$$\text{Sample size} = \frac{\left(\left(Z_{\frac{\alpha}{2}} \sqrt{2\bar{p}(1-\bar{p})} \right) + \left(Z_{1-\beta} \sqrt{p_v(1-p_v) + p_u(1-p_u)} \right) \right)^2}{(p_u - p_v)^2}$$

Where :

- \bar{p} = mean incidence proportion with outcome
- p_v = incidence proportion with outcome in vaccinated animals
- p_u = incidence proportion with outcome in unvaccinated animals
- $Z_{\frac{\alpha}{2}}$ = Two-sided percentage point from standardised normal distribution corresponding to required significance level. For 5%, this is 1.96.
- $Z_{1-\beta}$ = One-sided percentage point from standardised normal distribution corresponding to 100 – power (β). For 80% power, this is 0.84

To confirm the absence of an adverse event

$$n = \left(1 - \alpha^{\frac{1}{D}} \right) \times \left(N - \frac{(D-1)}{2} \right)$$

- n = sample size
- N = population size
- α = 1 – confidence level (as a proportion) = e.g. 0.05
- D = estimated minimum number of diseased animals ($= N \times p$)
- p = expected minimum prevalence

Annex 2. Example recording form

Name of the farm: _____ Farm ID number: _____
 Farm owner/manager: _____ Farm address: _____
 Date of vaccination: _____ Vaccine batch: _____
 Production stage: _____ Number of vaccinated pigs: _____

Month:	Day																																			
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31					
Clinical signs*																																				
Fever																																				
Weakness																																				
Inactivity																																				
Recumbency																																				
Lack of appetite or reduce food intake																																				
Skin haemorrhage †																																				
Joint swelling or arthritis																																				
Vomiting																																				
Diarrhoea																																				
Blood in diarrhoea																																				
Blood in urine																																				
Ocular discharge																																				
Abortion (pregnant sows)																																				
^																																				
^																																				
Mortality																																				
Pigs vaccinated died																																				
Pigs not vaccinated died																																				

*Please record the number of pigs daily with each observed clinical sign.

†Redness of skin on ears, abdomen or legs.

^ Use the blank cells to add clinical signs that are not listed

Additional comments / observations



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It's everyone's health.