



Centre for Applied One Health
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Guidelines for ASF vaccines: field evaluation and post-vaccination monitoring

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World Organisation
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Vaccine evaluation

Trial phase	Sample size	Outcomes assessed	Veterinary equivalent
Phase I	10-100	Safety, immunogenicity with different doses and schedules.	Equivalent studies are performed.
Phase II <i>Sometimes combined with phase I</i>	100-500	Immunogenicity and safety with greater precision.	
Phase III <i>Conducted if safe if safe and immunogenic</i>	1000 >100,000	Vaccine efficacy and sometimes immune correlates (field trials).	Extensive challenge studies <u>with limited field trials</u> to assess safety, immunogenicity and efficacy.
Phase IV <i>Post-licensure</i>	Observational studies within the vaccination programme.	Vaccine effectiveness and safety in the field.	<u>Rarely performed.</u> Post vaccination seroconversion or post outbreak evaluations are more common.

WOAH Standards on ASF Vaccines

Outline of production and minimum requirements for vaccines

- Characteristics of the seed virus
 - Biological characteristics of the master seed virus
 - Quality criteria (sterility, purity, freedom from extraneous agents)
 - Validation as a vaccine strain
- Method of manufacture
- Requirements for regulatory approval
 - Manufacturing process
 - Safety requirements

Controlled studies vs reality in the field

The sales pitch



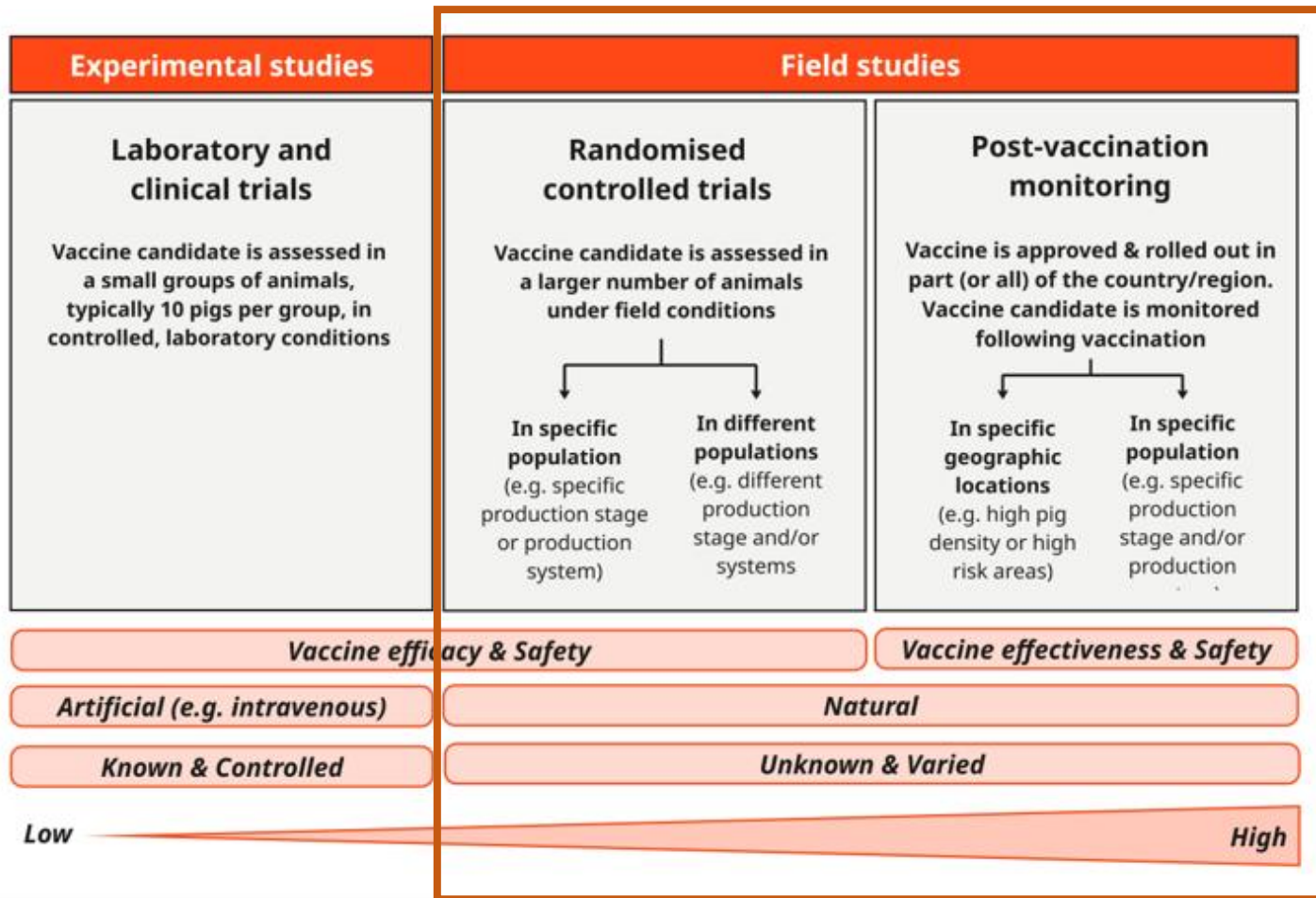
High internal validity
Poor external validity

Some real-world experiences



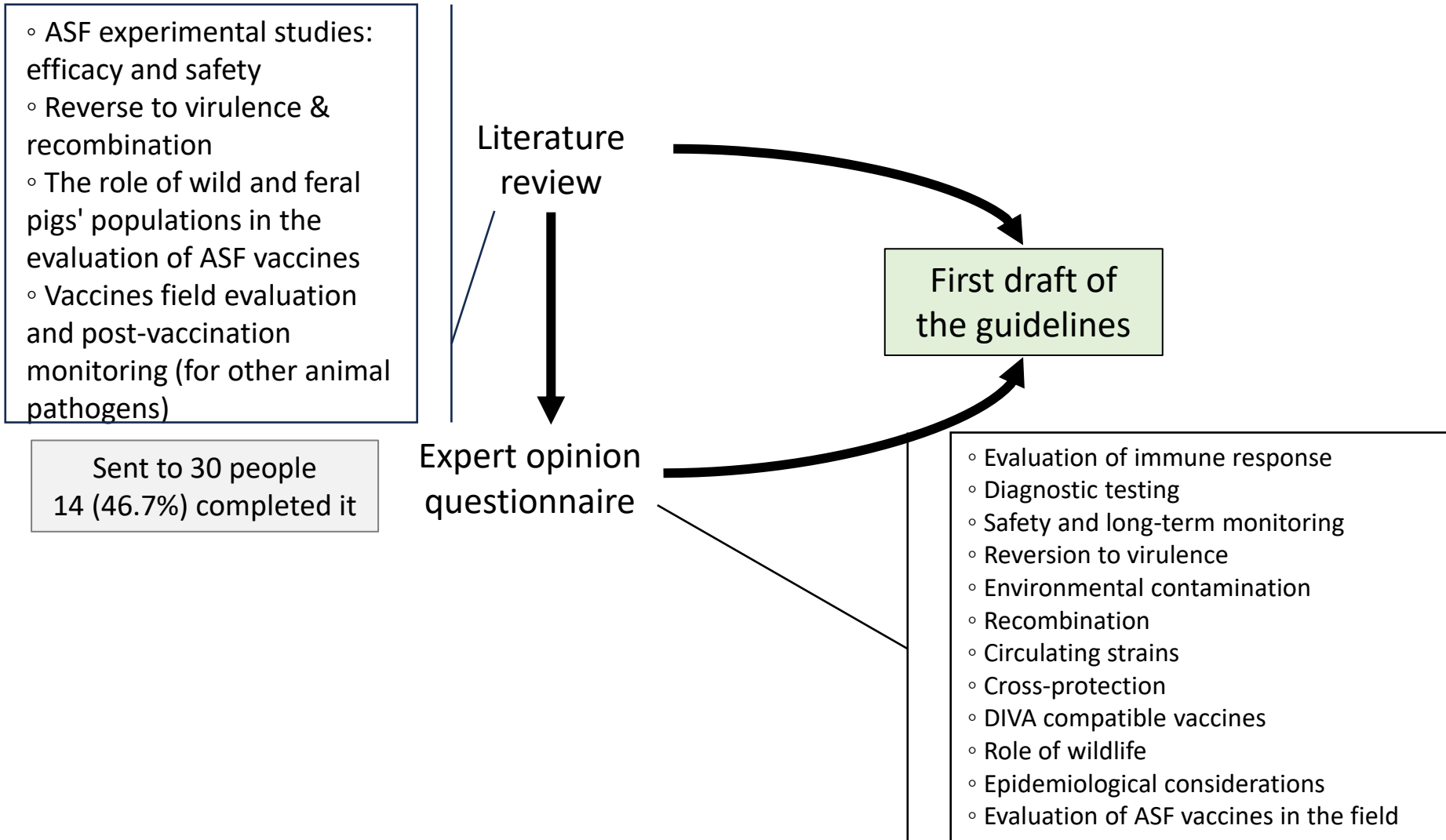
Requires knowing the
local context.

State of play of the guidelines



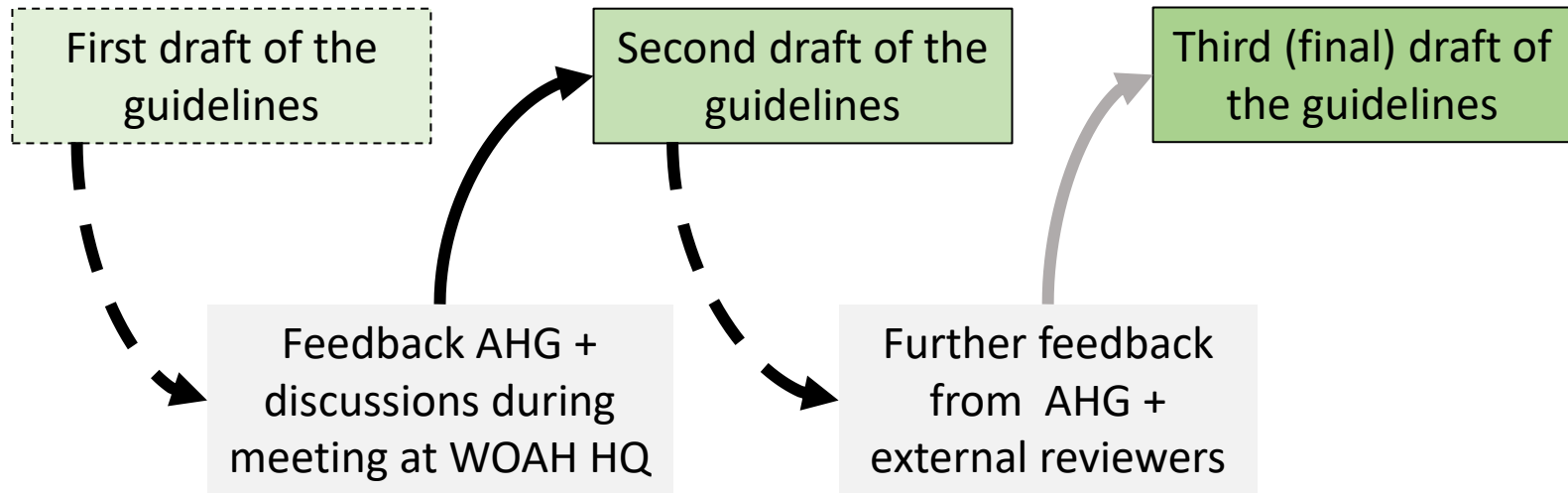
State of play of the guidelines

The process



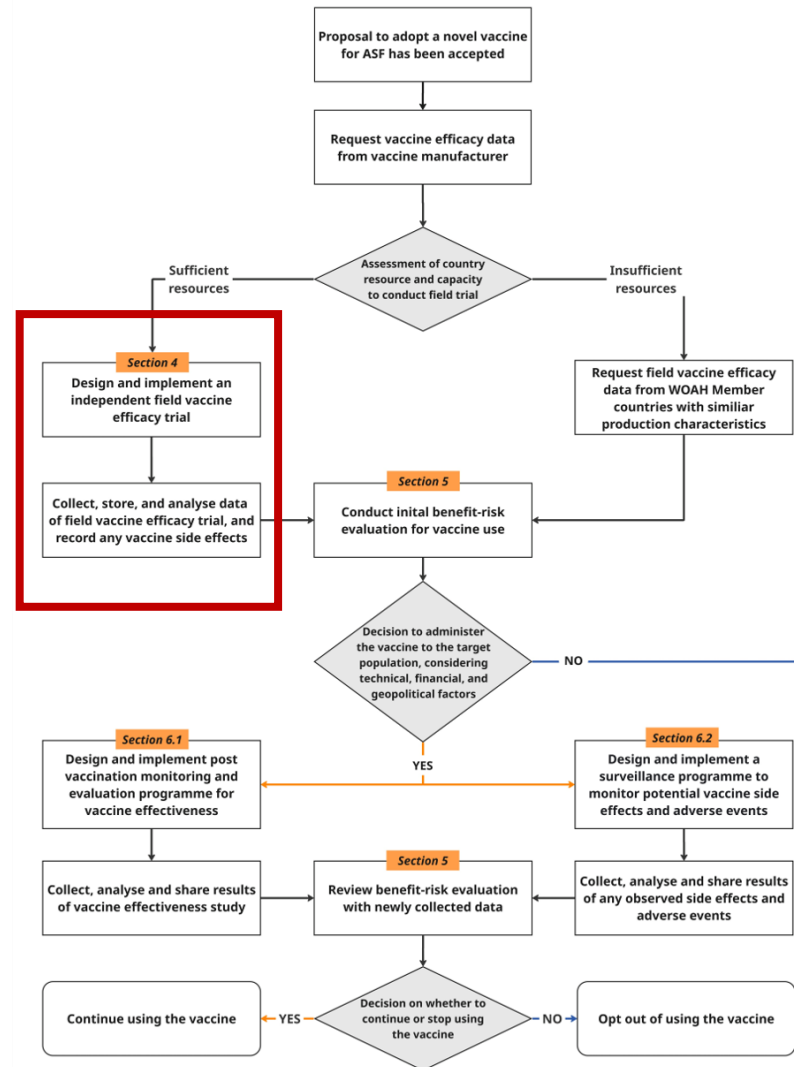
State of play of the guidelines

The process



[Guidelines for African swine fever \(ASF\) vaccines: field evaluation and post-vaccination monitoring](#)

Vaccine efficacy and safety in the field



Vaccine efficacy and safety in the field – case definition

Case definition

Before designing a vaccine efficacy study, the case definition for ASF should be clearly defined.

Chapter 15.1 of the WOAHA Terrestrial Animal Health Code states that *the definition of infection with ASFV entails either isolation of ASFV from a suid or detection of antigen, nucleic acid or antibodies specific to ASFV from an animal, with current or recent ASF clinical signs (or epidemiologically linked to a confirmed case).*

This definition has a purpose for official reporting.

For vaccine evaluation, a case definition specifies the criteria by which cases are identified and counted, based on what the vaccine meant to protect against (e.g. mortality, severe clinical signs or transmission)

Vaccine efficacy and safety in the field - outcome

Outcome

Before performing a vaccine efficacy study in the field, **the outcome(s) of interest need(s) to be clearly defined to guide key design elements of the study.**

Study outcome(s) should reflect the main objective of the vaccination programme **in the context of the country's national/regional ASF control programme**, where the goals may differ between regions or for different production systems.

Vaccine efficacy and safety in the field

Scenario 1

Region where ASFV is endemic

Objectives of the national ASF control programme:

- Reduce the number of ASF outbreaks
- Minimize associated production impacts

Objectives of the vaccination programme:

- Decrease ASFV transmissibility
- Reduce associated morbidity and mortality rates

Case definitions:

- A clinical sign score of 10 or above (See Table 1)
- Pig health deviation from baseline health survey

Outcome measures of the vaccination programme:

- New cases of ASF (based on case definition)
- Change in production parameters (e.g. weight)
- Variations in morbidity or mortality rates

Scenario 2

Region previously ASF-free, where ASF is newly detected

Objectives of the national ASF control programme:

- Regain ASF-free disease status

Objectives of the vaccination programme:

- Decrease ASFV transmissibility
- Assist in eradicating ASFV from pig population

Case definitions:

- At least two clinical signs consistent with ASF, along with the detection of antigen or nucleic acid specific to ASFV

Outcome measures of the vaccination programme:

- New cases of ASF (based on case definition)

Vaccine efficacy and safety in the field – study design

Study design

- Randomised controlled trials (RCT) are considered the gold standard method for evaluating vaccine efficacy.
- It compares at least two groups (referred to as 'arms') - one group receives the vaccine candidate under assessment, while the other usually receives a placebo (or a vaccine for a different disease).

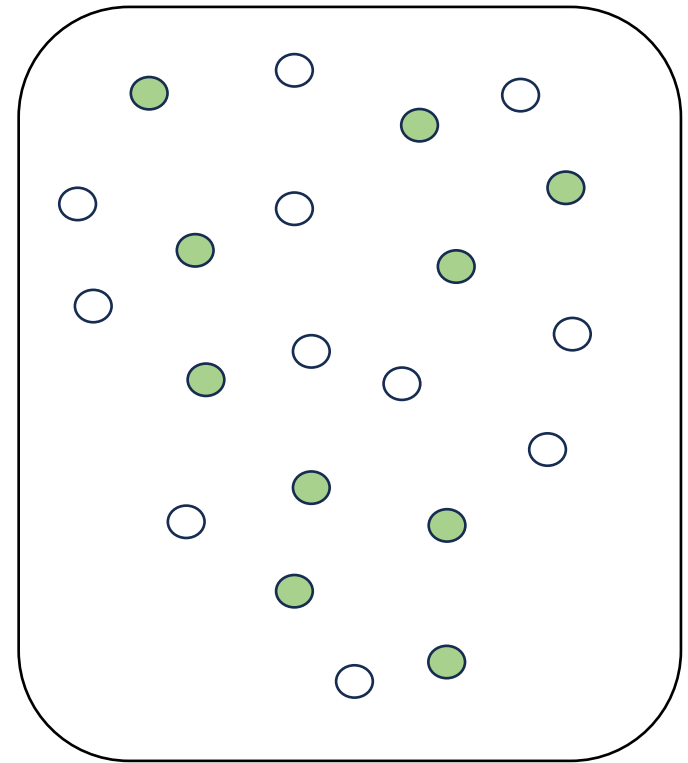
These trials can vary in design depending on the objectives and resources available, and can be conducted at either the individual (pig) or cluster level (e.g. pen, farm or village).

Vaccine efficacy and safety in the field - RCT study designs

Individual randomization

Pigs within the same group (e.g. farm, pen, village) will 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 will be a multisite randomised control trial (MRCT).



● Candidate vaccine

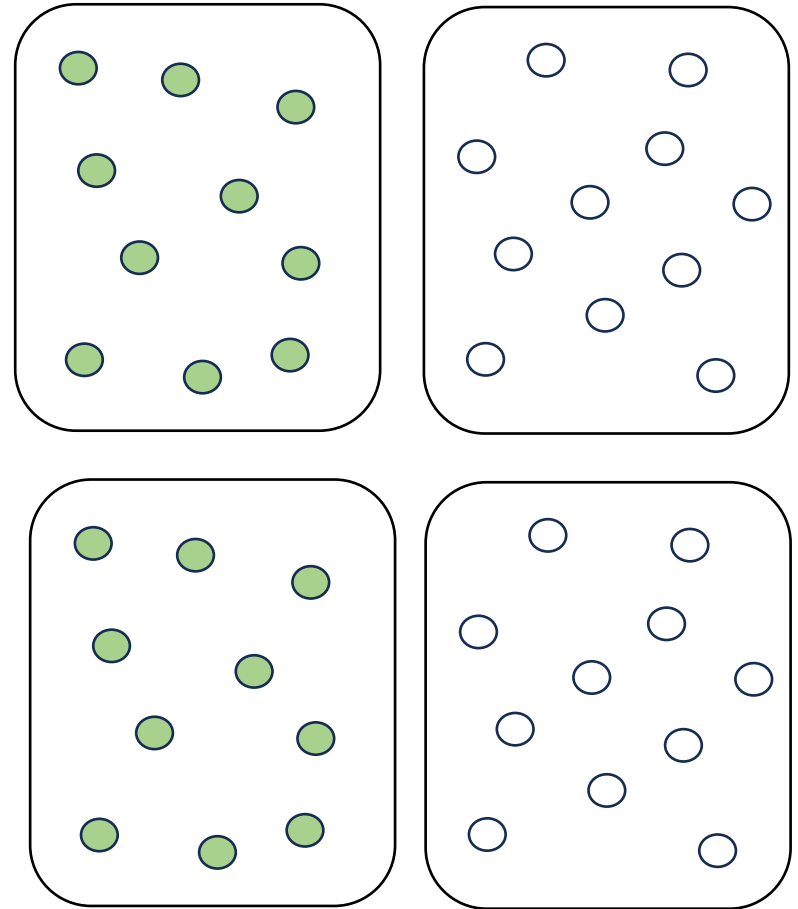
○ Placebo

Vaccine efficacy and safety in the field - RCT study designs

Cluster randomization

The farms (clusters) are separated into two or more groups, and all the animals within each cluster will receive either the candidate vaccine or the placebo (or vaccine unrelated to the target disease).

- Candidate vaccine
- Placebo

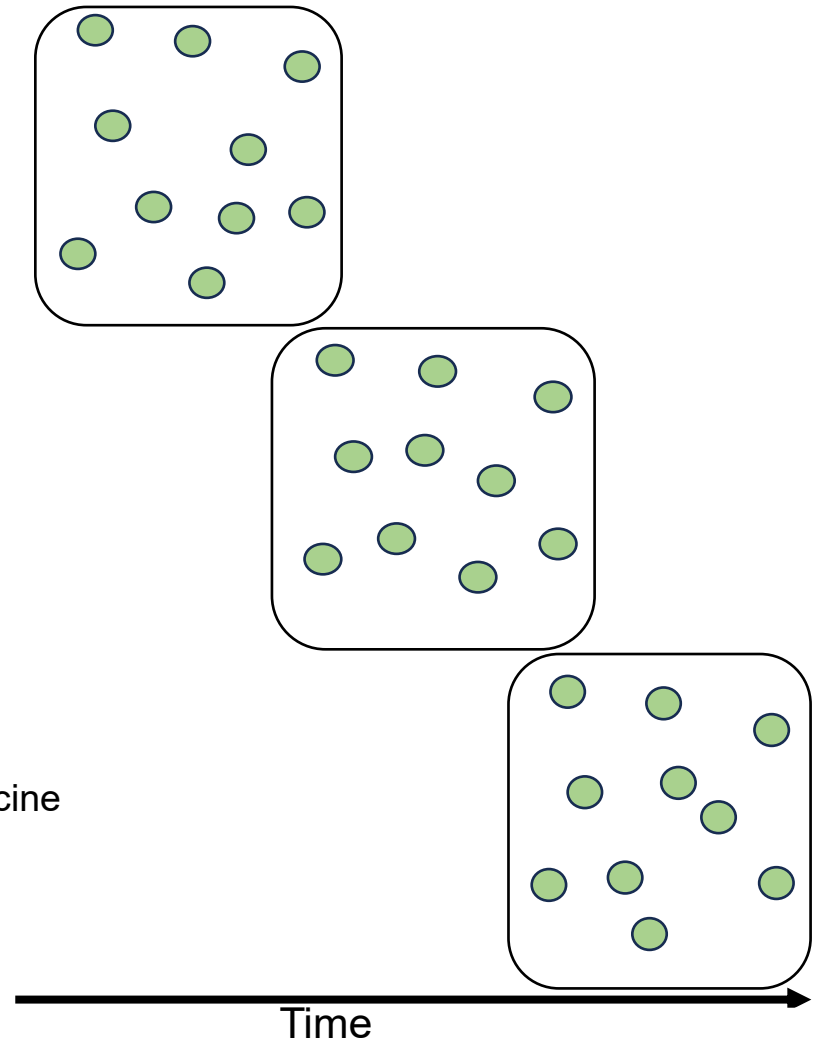


Vaccine efficacy and safety in the field - RCT study designs

Stepped wedge

All the farms (clusters) receive the candidate vaccine at different times (steps) of the study (i.e., there is no control group). The timing at which the cluster received the intervention is randomised.

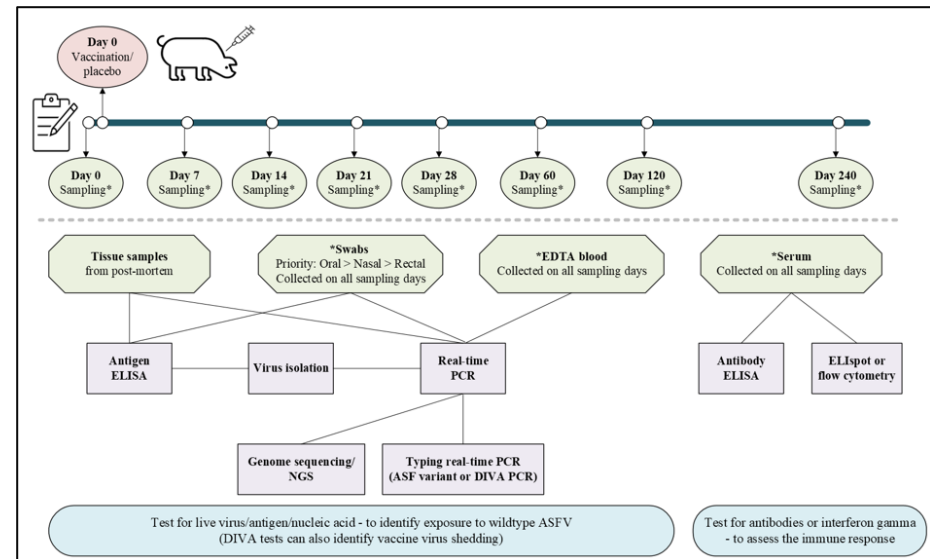
- Candidate vaccine
- Placebo



Vaccine efficacy and safety in the field - RCT study designs

Other points to consider:

- Study site selection
- Ethical considerations
- Sample size
- Inclusion and exclusion criteria
- Blinding
- Baseline visit
- Vaccination, sampling and data collection protocol

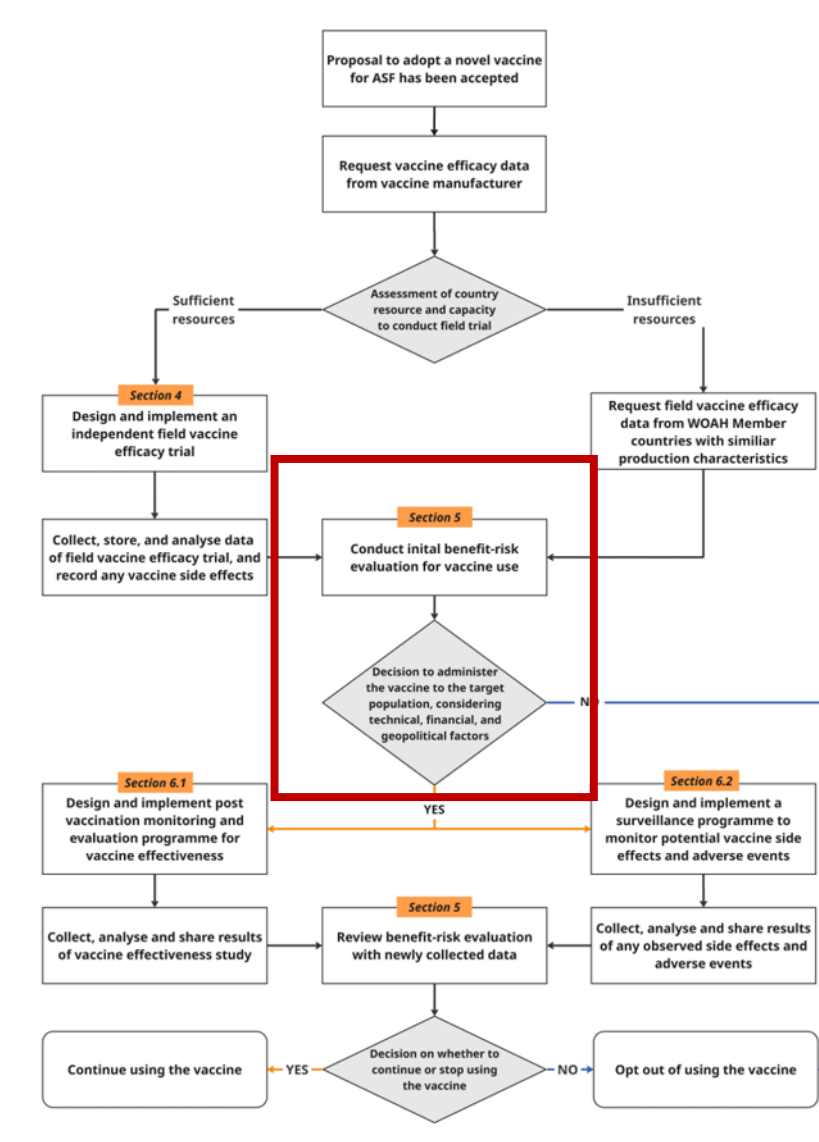


So, what is the most 'appropriate' design?

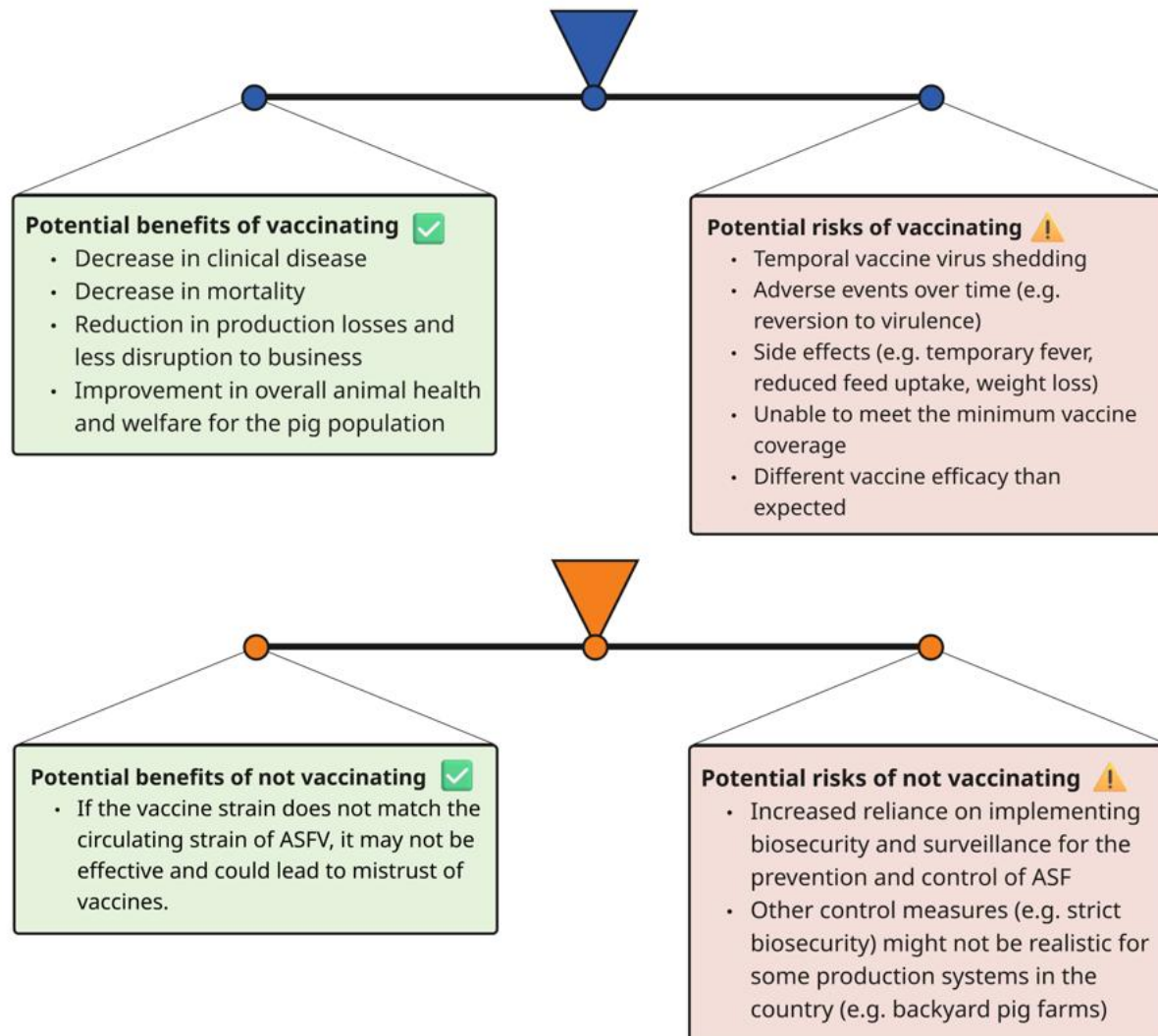
It depends...



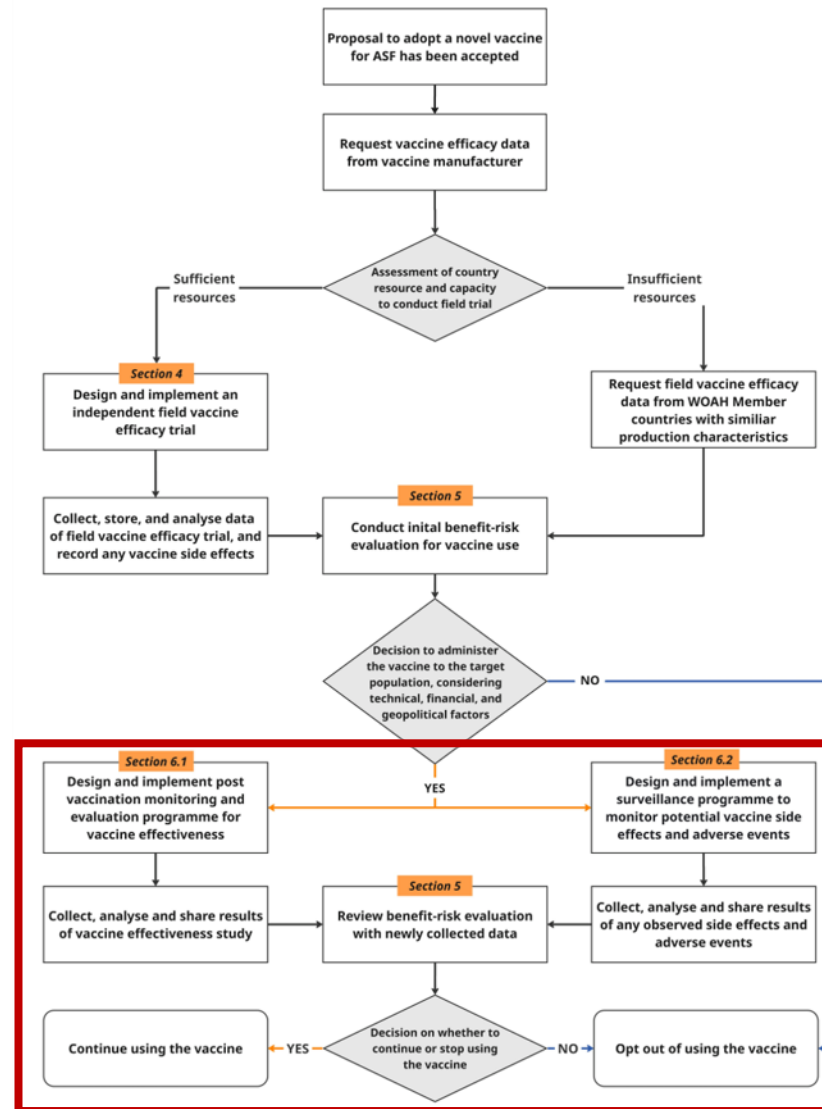
Benefit-risk assessment



Benefit-risk assessment



(Field) Post-vaccination monitoring



(Field) Post-vaccination monitoring

ASF vaccination should be considered as **one of the many tools for ASF prevention and control**, and should be **integrated within a comprehensive prevention and control programme** that may incorporate measures such as compartmentalisation, movement restrictions, and biosecurity improvements.

(Field) Post-vaccination monitoring - vaccine effectiveness

In contrast to vaccine efficacy studies, vaccine effectiveness studies are essential for evaluating how vaccines perform in real-world settings.

If there is an official programme, **vaccine effectiveness studies assess the vaccination programme as a whole**

(Field) Post-vaccination monitoring - vaccine effectiveness

Study design

Observational studies, such as **case-control** and **cohort studies**, are commonly used.

Case-control study	Cohort study
Compares the odds of vaccination in individuals or herds who developed the outcome of interest (cases) versus those who did not (controls) during an outbreak.	Follows vaccinated and unvaccinated pigs (or herds) over time , comparing disease incidence.

(Field) Post-vaccination monitoring - vaccine effectiveness

Outcomes to be **measured** should be linked to the objective of the control programme and defined in advance.

Aim of the control programme	Potential outcomes measures
Reduction in the number of ASF outbreaks in the country	◦ Reduction in incidence of ASF outbreaks
Eradication in the country and return to free status.	◦ Reduction in transmissibility

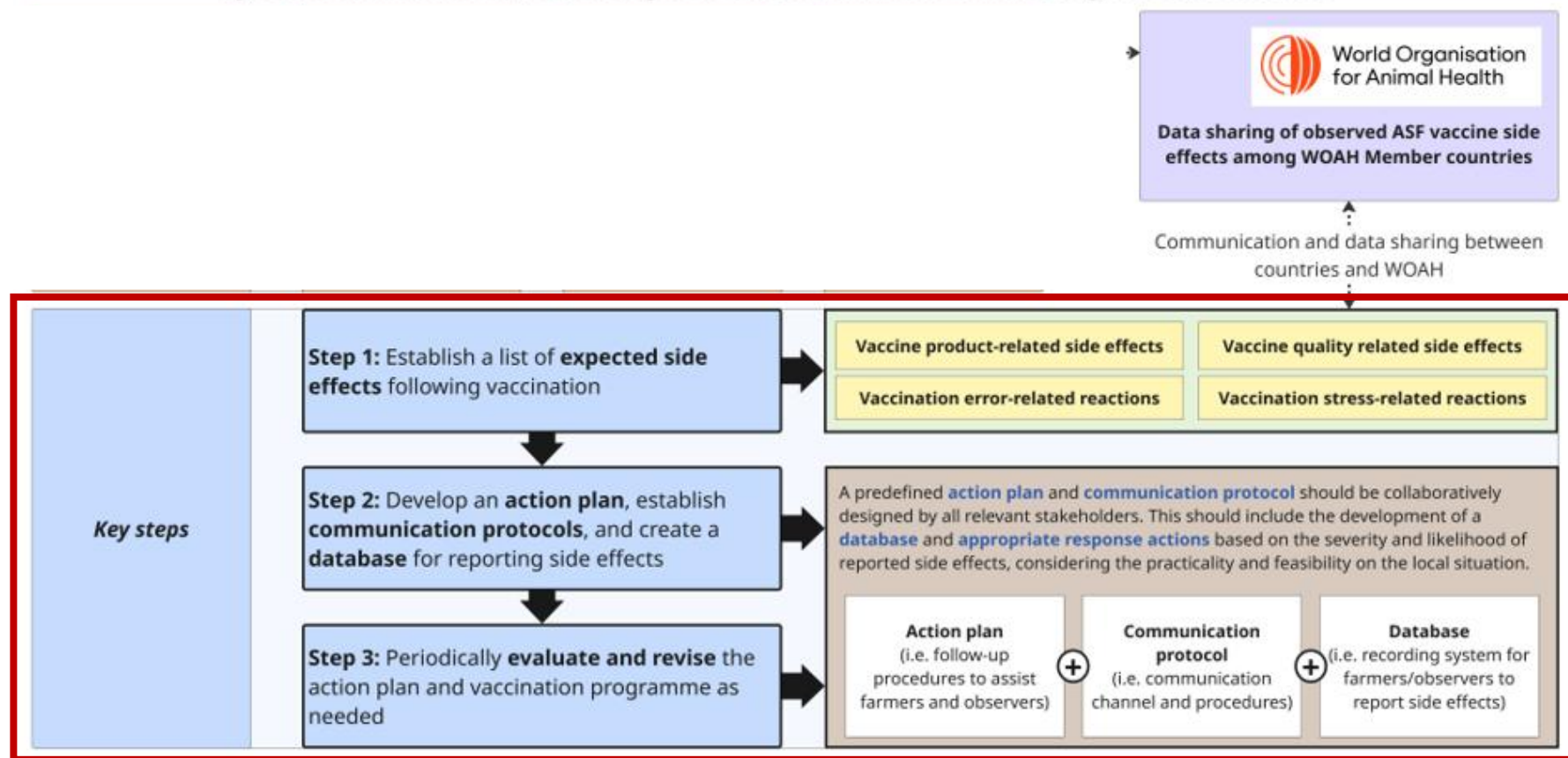
(Field) Post-vaccination monitoring - Pharmacovigilance

Post-vaccination monitoring of side effects (pharmacovigilance)

Pharmacovigilance and ongoing monitoring of vaccinated pig populations is crucial for assessing vaccine effectiveness, to maintain programme confidence and identify side effects or adverse events post-vaccination

(Field) Post-vaccination monitoring - Pharmacovigilance

Systematic framework for post-vaccination monitoring of side effects



Knowledge gaps that increase uncertainty

- **Immune (humoral and cellular) response:** Correlates of protection have not yet been established for ASFV.
- **Differentiating Infected from Vaccinated Animals (DIVA):** until today, there are currently no standardised tests that can be used to differentiate between vaccinated and infected animals in the population.
- **Genomics:** Whole genome sequencing is key for detecting reversion to virulence and recombination. However, it is expensive, making it difficult for many countries to perform on a regular basis.

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