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African Swine Fever Vaccine Research and Deployment: A Review of Challenges and Future Directions in Vietnam's Supervised Rollout

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Abstract

African swine fever (ASF) continues to cause billions of dollars in global losses each year, disrupting pork supply chains and food security across Asia. This review analyzes the persistent gap between laboratory success and field performance of African swine fever vaccines, emphasizing live attenuated vaccines (LAVs) and hybrid next-generation platforms. It synthesizes recent findings on gene-deleted LAVs, encapsulin-based subunits, and mRNA or nanoparticle boosters that collectively aim to balance efficacy, safety, and DIVA compatibility. Key challenges include inconsistent protective efficacy, undefined immune correlates, and biosafety risks such as virulence reversion or recombination. Manufacturing constraints—dependence on porcine cell substrates, quality assurance, and scalability—compound system-level obstacles related to fragmented regulation and limited pharmacovigilance. Vietnam's supervised rollout of NAVET-ASFVAC and AVAC ASF LIVE, with millions of doses deployed under strict monitoring, exemplifies a risk-managed model for national implementation. Looking ahead, coordinated regional governance, standardized challenge models, and harmonized regulatory frameworks are essential to translate next-generation hybrid vaccines into safe, scalable, and equitable ASF control strategies.

Keywords

African swine fever virus, live attenuated vaccines, vaccine safety, correlates of protection, DIVA strategy, regulatory policy

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Introduction

African swine fever (ASF) has reemerged as a global threat to pig production, causing profound economic and social disruption. African swine fever virus (ASFV) is a large double-stranded DNA virus belonging to the family *Asfarviridae*. It primarily replicates in cells of the monocyte–macrophage lineage and causes a highly

contagious and often lethal disease in domestic pigs and wild boars. ASFV exhibits substantial genetic diversity, with genotype II and its variants currently responsible for most outbreaks in Asia. This genetic variability, together with complex host–pathogen interactions and immune evasion mechanisms, poses major challenges for the development of safe, effective, and broadly protective vaccines. China's 2018 outbreak led to the loss of more than 100 million pigs, driving pork prices upward and destabilizing food security across Asia (Acosta *et al*., 2023). Global economic losses now exceed tens of billions of U.S. dollars, establishing ASF as one of the most devastating animal health crises of the century. As biosecurity and stamping-out alone remain insufficient, vaccination has become indispensable for long-term management (Auer *et al*., 2024).

Inactivated and subunit vaccines have failed to elicit durable immunity, underscoring ASFV's immunobiological complexity and immune evasion strategies (Pedrera *et al*., 2024). Consequently, research has shifted toward live attenuated vaccines (LAVs) generated by targeted deletions of key virulence genes (Chen *et al*., 2020; Gladue & Borca, 2022; Tran *et al*., 2022; Sunwoo *et al*., 2024). These candidates have demonstrated strong efficacy in controlled settings, although genotype II LAVs have shown limited breadth of protection across diverse ASFV strains.

Vietnam has conditionally licensed NAVET-ASFVAC and AVAC ASF LIVE and implemented large-scale field use under supervised conditions. By mid-2024, deployment had expanded nationwide, supported by QR-code traceability and post-marketing surveillance systems (WOAH, 2023; Chuong *et al*., 2025). This experience is increasingly recognized as one of the most comprehensive applications of ASF LAVs under endemic conditions (Ngo *et al*., 2026).

Despite these advances, significant challenges persist. Genetic instability, virulence reversion, and recombination with field strains continue to raise biosafety concerns, exemplified by the detection of a vaccine-like variant in an unvaccinated herd (Nguyen *et al*., 2025). Additional barriers include inconsistent protection (Chu *et al*., 2024), undefined immune correlates (Pedrera *et al*., 2024; Sunwoo *et al*., 2024), reduced efficacy in pregnant sows (Lee *et al*., 2025), and constraints in large-scale manufacturing, regulation, and integration with farm-level biosecurity (Auer *et al*., 2024).

This article examines the biological, manufacturing, and regulatory dimensions of ASF vaccination, using Vietnam's supervised rollout as a case study to define pathways for scaling safe, effective, and sustainable vaccine strategies (Tran *et al*., 2022; Chuong *et al*., 2025; Diep *et al*., 2025).

Current Landscape

In 2025, the African swine fever (ASF) vaccine field was cautiously optimistic. LAVs dominated, while subunit, vectored, and mRNA platforms advanced in preclinical development. LAVs showed strong efficacy under controlled conditions (Chen *et al*., 2020; Gladue & Borca, 2022; Tran *et al*., 2022), with recent meta-analytical synthesis confirming consistently higher protection rates than alternative platforms despite variability across strains and study designs (Ntakiyisumba *et al*., 2025). Rational deletions of representative virulence genes conferred robust protection in European and Asian pigs, with MGF505-2R activating the cGAS-STING pathway to enhance attenuation (Sunwoo *et al*., 2024). Vu & McVey (2024) reviewed gene-deleted LAVs, contrasting single- and multi-gene strategies with differential safety and efficacy across laboratory and field settings. Still, genotype II strains conferred incomplete protection against recombinant I/II variants (Diep *et al*., 2024). Borca *et al*. (2025) reported that ASFV-G-ΔI177L yielded strong homologous but only partial cross-protection, underscoring the limited breadth of genotype II-derived LAVs.

Subunit and vectored vaccines target conserved proteins such as p72, p54, and CD2v. These platforms offer high safety and are compatible with DIVA but have shown inconsistent immunogenicity and often require optimized adjuvants or heterologous prime–boost regimens (Zhang *et al*., 2024), consistent with lower and more variable protection than LAVs

(Ntakiyisumba *et al*., 2025). Certain non-neutralizing responses, such as anti-pA137R antibodies that enhance ASFV pathogenicity, highlight the importance of antigen selection (Zhai *et al*., 2025). Zhang *et al*. (2025) showed that SpyTag/SpyCatcher-conjugated p54 nanoparticles enhanced receptor binding and induced cross-neutralizing antibodies against genotype II and recombinant I/II strains. mRNA vaccines offer scalable and safe alternatives but remain challenged by durability, thermostability, and field validation (Auer *et al*., 2024; Zhang *et al*., 2023).

Vietnam authorized NAVET-ASFVAC and AVAC ASF LIVE in 2023 under strict monitoring, pharmacovigilance, and genomic surveillance (WOAH, 2023; Diep *et al*., 2025). By mid-2024, large-scale administration had expanded across multiple provinces and production systems, including pregnant sows (WOAH, 2023; Lee *et al*., 2025). These programs generate essential data on immunogenicity, biosafety, residual virulence, and reduced efficacy against variants (Chu *et al*., 2024; Nguyen *et al*., 2025).

Lessons from 2020–2025 stress surveillance and risk management. Spatiotemporal outbreak data have informed vaccination timing (Bui *et al*., 2025), while international coordination through WOAH and regional authorities has supported knowledge exchange and technology transfer despite limited production, cold-chain gaps, and fragmented regulation (Auer *et al*., 2024; WOAH, 2023). Genetic microvariants within established genotypes further complicate control (O'Dwyer *et al*., 2025).

In summary, the 2025 ASF vaccine landscape is defined by LAV dominance, continued progress in subunit, vectored, and mRNA approaches, and increasing emphasis on governance and surveillance. These advances demonstrate progress but also expose the biological and translational challenges that must be addressed to achieve safe, equitable, and sustainable ASF control.

Biological and Translational Challenges

Despite notable progress, African swine fever (ASF) vaccine development, approval, and deployment remain constrained by major biological and translational challenges, particularly for LAVs and emerging platforms. These challenges span incomplete understanding of immune correlates, vaccine design limitations, safety concerns, and translational barriers in diverse field settings.

Immune correlates and antigenic targets

Protective immune correlates remain incompletely defined. Most vaccine candidates, especially LAVs, elicit strong humoral responses; however, antibodies alone do not confer sterilizing or cross-genotype immunity (Chuong *et al*., 2025; Zhai *et al*., 2025). Cell-mediated immunity, particularly $CD8^+$ cytotoxic T lymphocytes (CTLs), plays a central role in eliminating infected macrophages and is associated with IFN-γ production. Studies using MGF360/505-deleted strains highlight the importance of multifunctional T-cell responses in protective immunity (Gladue & Borca, 2022; Sunwoo *et al*., 2024). Intradermal immunization with attenuated ASFV also induces durable $CD8^+$ memory responses (Pedrera *et al*., 2024).

Recent systems immunology analyses show that protection depends on coordinated immune responses rather than individual immune components. Integrated analyses of cytokine kinetics, leukocyte populations, and whole-blood transcriptomic signatures indicate that early innate activation with balanced inflammatory responses predicts protection, whereas prolonged inflammation correlates with pathology (Madden *et al*., 2025). Protective responses are also associated with activated $CD8^+$ T cells, modulation of NK cell subsets, stabilization of myeloid populations, and coordinated upregulation of interferon-stimulated genes, antigen-processing pathways, and T-cell activation modules (Madden *et al*., 2025).

Emerging evidence suggests that T follicular helper (Tfh) cells and germinal-center B-cell responses contribute to antibody quality and durability, although their roles in ASFV protection remain incompletely defined. Identification of reliable biomarkers therefore requires integration of cytokine signatures, cellular immune profiling, and longitudinal

transcriptomic analyses. Systems vaccinology approaches combining multi-omics and computational modeling provide a framework for defining immune correlates and guiding vaccine design (Zhang *et al*., 2023; Madden *et al*., 2025).

These findings support a shift from single immune correlates to systems-level immune signatures. **Table 1** summarizes major ASFV proteins and their immunological roles relevant to vaccine design, immune recognition, and correlate-of-protection discovery.

LAV design, immunology, and translational safety

Building on these immunological foundations, LAVs remain central to ASF vaccine development, where gene deletion strategies, immune responses, and safety considerations are closely interconnected.

Targeted deletions increasingly focus on virulence-associated genes such as I177L, CD2v, DP148R, and I73R. While single-gene deletions may preserve immunogenicity, multi-gene approaches improve genetic stability and reduce reversion risk, particularly when combined with genomic surveillance (Vu & McVey, 2024). Deletion of I73R in the Georgia strain yielded safe attenuation with strong immunogenicity (Liu *et al*., 2023), whereas deletions of I177L and DP148R conferred robust protection against Vietnamese field strains (Chen *et al*., 2020; Tran *et al*., 2022). MGF505-2R deletion also enhances attenuation while maintaining efficacy (Sunwoo *et al*., 2024).

Despite these advances, the immunological consequences of gene deletions remain incompletely characterized. The absence of validated biomarkers contributes to inter-study variability, highlighting the need for longitudinal immunoprofiling, single-cell transcriptomics, and multiplex cytokine assays (Zhang *et al*., 2023). Complementary strategies, including DIVA marker integration and genetic stability monitoring, remain essential (Gladue & Borca, 2022; Borca *et al*., 2025). Alternative delivery systems such as encapsulin-p54 nanoparticles also expand protective breadth while providing DIVA-compatible options (Zhang *et al*., 2025).

Field evidence illustrates both the potential and limitations of LAVs. AVAC ASF LIVE induces strong IgG neutralization and $CD8^+$ activation, resulting in durable protection (Diep *et al*., 2025), whereas efficacy varies across

Table 1. Major ASFV Proteins, Functions, and Immunological Relevance

Protein	Function	Immunogenicity	Vaccine Relevance	References
p72 (B646L)	Major capsid protein; structural integrity	High (strong antibody responses)	Diagnostic marker; subunit vaccine candidate	Gladue & Borca (2022); Zhai et al. (2025)
p54 (E183L)	Viral attachment and entry	High	Target for neutralizing antibodies; nanoparticle delivery (encapsulin-p54)	Sunwoo et al. (2024); Zhang et al. (2025)
p30 (CP204L)	Early infection protein; host interaction	High	Early immune marker; subunit vaccine component	Zhai et al. (2025)
CD2v (EP402R)	Hemadsorption; immune modulation	Moderate–High	Key for cross-protection; deletion affects virulence and immunity	Monteagudo et al. (2017); Borca et al. (2020)
pA137R	Immune modulation (possible ADE-related)	Variable	Requires careful evaluation due to potential ADE effects	Zhai et al. (2025)
MGF360/505	Immune evasion (IFN suppression)	Low (indirect)	Targets for attenuation; enhances innate activation when deleted	Gladue & Borca (2022); Sunwoo et al. (2024)

genetically diverse ASFV strains despite high homologous protection under controlled conditions (Diep *et al*., 2024; 2025).

Antibody-dependent enhancement (ADE), although not demonstrated in ASFV, remains a theoretical concern. Mitigation strategies include prioritizing protective antigens, balancing humoral and cellular responses, and incorporating ADE screening into preclinical pipelines (Gladue & Borca, 2022; Sunwoo *et al*., 2024; Zhai *et al*., 2025).

Translational data from Vietnam also highlight safety challenges. Although AVAC ASF LIVE achieved 90–100% protection with low adverse-event rates (Diep *et al*., 2025), reproductive failures associated with vaccine-like variants raise concerns regarding reversion, recombination, or immune-mediated effects (Nguyen *et al*., 2025; Zhai *et al*., 2025). These findings have led to gestation-stage–specific vaccination policies. Vaccination during early to mid-gestation is generally safe, whereas late gestation is associated with elevated risk under certain conditions (Lee *et al*., 2025; Liu *et al*., 2026). Variability across breeds and production systems continues to complicate large-scale implementation (WOAH, 2023; MARD, 2023; Diep *et al*., 2025).

Platform comparison and development constraints

Beyond LAVs, ASFV vaccine development requires comparative evaluation of emerging platforms, each with distinct immunological profiles, safety characteristics, and translational constraints.

LAVs remain dominant because they mimic natural infection and induce strong Th1-biased responses, including $CD8^+$ T-cell activation, IFN-γ production, and macrophage engagement (Monteagudo *et al*., 2017; Gladue & Borca, 2022; Chu *et al*., 2024). However, safety concerns, including residual virulence and recombination, continue to limit broader application.

In contrast, mRNA and nanoparticle-based vaccines offer improved safety and antigen precision. These platforms enable controlled antigen expression and coordinated humoral and cellular responses (Zhang *et al*., 2023; Sunwoo *et al*., 2024; Lee *et al*., 2026). Nanoparticle formulations further enhance antigen stability, multivalent display, and broader neutralization across ASFV variants (Zhang *et al*., 2024; Zhang *et al*., 2025; Lee *et al*., 2026).

Development timelines differ substantially across platforms. LAVs require prolonged validation, including attenuation stability, biosafety testing, and large-scale field trials. Subunit and nanoparticle vaccines generally require optimization to achieve sufficient immunogenicity, whereas mRNA platforms enable rapid antigen design despite continuing challenges in delivery, stability, and durability.

Gene deletion remains the basis of LAV development, with outcomes varying by viral background. CD2v deletion in BA71 (genotype I) produced safe, protective immunity, whereas similar deletions in Georgia 2007 (genotype II) resulted in incomplete attenuation (Monteagudo *et al*., 2017; Borca *et al*., 2020). Subsequent deletion of I177L achieved complete attenuation and sterile immunity, establishing a benchmark for modern LAV design (Borca *et al*., 2020). Advanced constructs such as ASFV-G-ΔI177L/ΔLVR have further demonstrated improved safety and efficacy, including in pregnant animals (Choi *et al*., 2025; Lee *et al*., 2025). **Figure 1** summarizes the comparative immune responses and trade-offs among LAV, mRNA, and nanoparticle vaccine platforms.

Integrated Research Priorities and Biosafety Framework

ASFV's complexity requires integrated research across immunology, virology, genomics, and bioengineering. Priorities include T-cell epitope mapping, adjuvant optimization, genome editing, variant surveillance, and next-generation vaccine platforms (Liu *et al*., 2023; Pedrera *et al*., 2024; Sunwoo *et al*., 2024; Zhang *et al*., 2024; Nguyen *et al*., 2025). Technology transfer and implementation remain limited in low- and middle-income countries because of inadequate BSL-3 facilities, skilled personnel, and regulatory capacity. Endemic regions such as Vietnam face additional challenges (Bui *et al*., 2025), compounded by ASFV microvariants in the Asia–Pacific region (O'Dwyer *et al*., 2025).

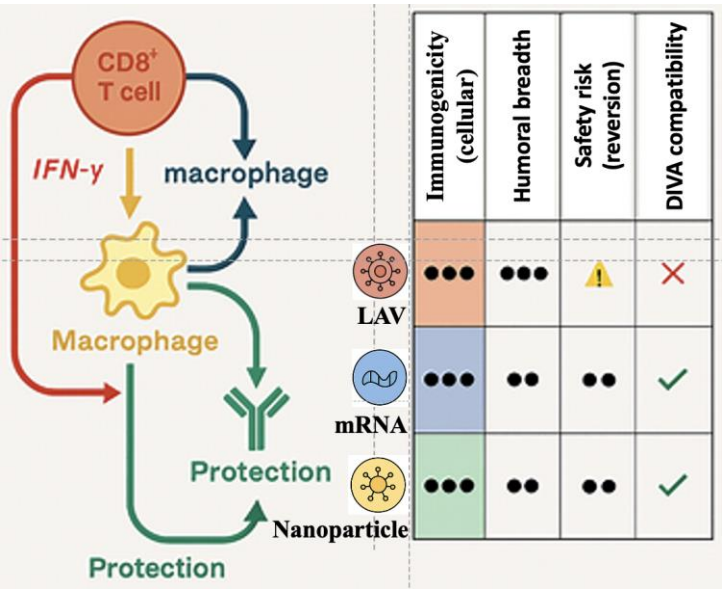


Figure 1. Comparative immune responses and platform trade-offs among ASF vaccine technologies (2025). Left: Simplified immune pathways illustrating dominant responses induced by LAV, mRNA, and nanoparticle vaccines, where line thickness reflects relative induction strength. LAVs primarily activate CD8⁺ T cells and macrophage–IFN-γ loops, while mRNA and nanoparticle platforms emphasize targeted antigen delivery and humoral balance. Right: Summary matrix comparing immunogenicity, humoral breadth, safety risk, and DIVA compatibility across platforms. Symbols indicate relative strength or concern (●●● = high, ●● = moderate, ○○ = low). Data synthesized from Monteagudo *et al*. (2017), Diep *et al*. (2025), and Zhang *et al*. (2023; 2025).

These constraints translate into biosafety risks associated with LAV deployment, summarized in **Table 2**. ASF vaccine development therefore requires an integrated framework combining gene deletion, immune correlate discovery, platform diversification, and biosafety governance. **Table 3** summarizes the major research priorities, including surveillance, next-generation platforms, and international collaboration.

Strategic integration and future directions

Hybrid vaccination strategies combining LAVs with mRNA or nanoparticle boosters may balance efficacy and safety. LAVs provide rapid outbreak control through strong cellular immunity, whereas next-generation platforms improve safety, precision, and DIVA compatibility (Monteagudo *et al*., 2017; Sunwoo *et al*., 2024; Diep *et al*., 2025; Nguyen *et al*., 2025). Gene deletion will remain central, supported by genomic surveillance and DIVA marker integration (Gladue & Borca, 2022; Borca *et al*., 2025).

As illustrated in **Figure 2**, targeted deletions such as CD2v and I177L enable rational attenuation while preserving immunogenicity. Multi-gene strategies with biosafety monitoring are essential for long-term stability and efficacy. Novel delivery systems such as encapsulin-based nanoparticles further expand next-generation vaccine development (Zhang *et al*., 2025).

Incorporating ADE screening into vaccine design further strengthens safety evaluation (Zhai *et al*., 2025). Systems vaccinology tools, including transcriptomics, epitope mapping, and repertoire profiling, can refine antigen selection and identify correlates of protection, supporting rational optimization of integrated vaccine strategies (Zhang *et al*., 2023; Chuong *et al*., 2025).

Targeted deletions of I177L, CD2v, I73R, and DP148R represent key approaches for rational attenuation in ASF LAVs. I177L and CD2v deletions provide stable, safe attenuation, while I73R and DP148R require enhanced biosafety monitoring (⚠). Dashed arrows indicate that reduced virulence may also confer broader protection potential through conserved antigenic and cellular responses (Monteagudo *et al*., 2017; Borca *et al*., 2020). Integration with DIVA markers and genomic surveillance underpins long-term biosafety and translational reliability.

Table 2. Safety Risks and Mitigation Strategies for Live Attenuated ASF Vaccines

Risk Group	Mandatory Measures (★) / Recommendations (☆)	International Examples & Notes	Scientific References
Residual Virulence / Reversion	★ Full deletion of validated core virulence genes (e.g., I73R where supported). ★ High-dose multi-generation/forced-passage testing to detect reversion. ☆ Targeted pre-licensure trials in pregnant sows and neonatal piglets; extended follow-up.	China: HLJ/18-7GD shows no reversion in trials. Vietnam: requires multi-round challenge testing under supervised deployment.	Chen *et al*. (2020); Diep *et al*. (2025)
Field Gene Recombination	★ Restrict LAV use in areas with co-circulating multiple genotypes or high recombination risk. ★ Routine molecular surveillance (NGS/metagenomics) of vaccine and field strains. ☆ Regional coordination to manage co-infection risks and sequence sharing.	EU: precautionary restrictions in recombination-prone zones. China & Vietnam: conduct batch genetic checks and genomic monitoring.	Gladue & Borca (2022)
Adverse Reactions	★ Standardized administration protocols (dose, route), certified vaccinators, and cold-chain control. ★ Mandatory veterinary training and clear reporting pathways. ☆ Rapid response teams for serious events.	Vietnam: mandatory post-marketing surveillance and investigation of serious events. China: integrates monitoring into veterinary regulation.	Chu *et al*. (2024); Diep *et al*. (2025)
Reproductive Impact	★ Separate pre-licensure safety trials in breeding herds with gestation-stage stratification (early, mid, late pregnancy) and defined monitoring windows (e.g., 28–90 days). ★ Implement gestation stage–specific vaccination guidelines, permitting vaccination in early–mid gestation while restricting late-pregnancy use based on risk profiling. ☆ Avoid routine late-pregnancy vaccination unless supported by robust safety and field validation data; apply only under controlled conditions with enhanced monitoring.	China: stage-stratified reproductive safety evaluation in LAV trials. Vietnam: operational restriction of late-gestation vaccination with ongoing field validation. Emerging evidence supports timing-dependent safety rather than universal restriction.	Chen *et al*. (2020); Lee *et al*. (2025); Nguyen *et al*. (2025); Liu *et al*. (2026)
General Risk Control & Operational Measures	★ Integrate vaccination with quarantine, sanitation, genomic stability testing, and batch release criteria under GMP. ☆ Transparent adverse-event data sharing, field training, and farmer communication.	Integrated systems in EU, Vietnam, and China combining vaccination, QR traceability, and surveillance.	WOAH (2023); MARD (2023)

Table 3. Future Strategies to Enhance ASF Vaccine Safety and Effectiveness

Research Direction / Solution	Key Contents / Specific Initiatives	Representative International References
Continuous Genetic-Epidemiological Surveillance	Gene sequencing systems and periodic serum sampling; multi-center NGS analysis to detect mutations, virulence reversion	Chen *et al*. (2020); Liu *et al*. (2023); Vu & McVey (2024); Chuong *et al*. (2025)
Next-Generation Vaccine Platforms	Investment in R&D for advanced platforms (e.g., mRNA, DNA/subunit, and nanoparticle vaccines); multi-layered virulence control in attenuated strains	Gladue & Borca (2022); Chu *et al*. (2024); Zhang *et al.* (2024)
Long-Term Field Trial Modeling	Multi-season, multi-breed, multi-zone trials; zoning vaccination to monitor viral drift	Chen *et al*. (2020); WOAH (2023); MARD (2023)
Standardized Veterinary Training & Community Communication	Intensive training for staff; structured communication for farmers on vaccination benefits and risks	Chuong *et al*. (2025)
Interdisciplinary & International Collaboration	Data sharing among scientists, regulators, producers; open-access epidemiology and adverse event reporting	Gladue & Borca (2022); Chu *et al*. (2024)
Long-Term Policy & Regulatory Management	Multi-center safety data for licensing; control of co-infections and recombination; regulatory updates	WOAH (2023); Bui *et al*. (2025)
Enhancing LAV Safety	Genetically stable strains (e.g., ASF-VH21), specialized cell lines, post-vaccination monitoring, technical training, exploring mRNA/nanoparticle boosters	Gladue & Borca (2022); Chu *et al*. (2024); Vu & McVey (2024); Chuong *et al*. (2025)

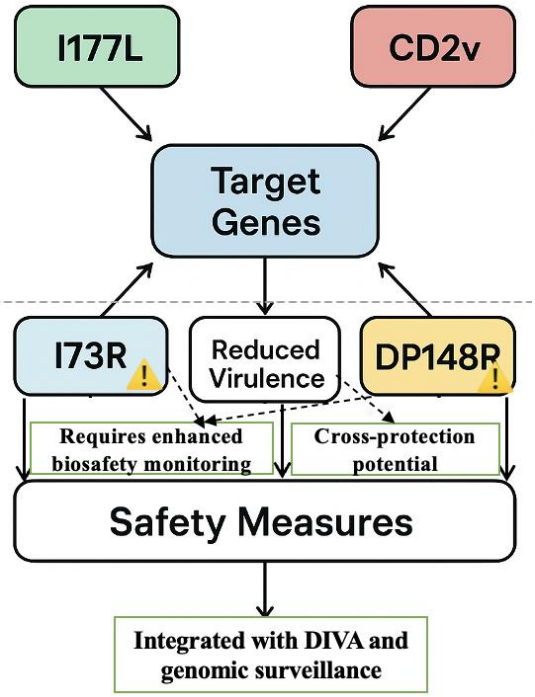


Figure 2. Gene Deletion Strategies and Safety Optimization in ASF LAVs (2025)

Manufacturing and Regulatory Challenges

The production, quality assurance, and regulation of ASF vaccines present interlinked challenges affecting safety, scalability, and implementation. Effective rollout requires robust production platforms, genomic stability monitoring, and biosafety compliance (Auer *et al*., 2024; WOAH, 2023). These concerns are particularly important for LAVs because residual virulence and genomic variability require rigorous oversight throughout production and post-deployment surveillance (Gladue & Borca, 2022; Chu *et al*., 2024). Gene-deleted strains such as ASFV-G-ΔI177L illustrate how molecular precision can reduce reversion risks and facilitate regulatory evaluation (Borca *et al*., 2020). Nevertheless, production bottlenecks and fragmented regulation continue to impede global adoption (Zhang *et al*., 2023).

Production platforms and bioprocessing constraints

ASFV replication in monocyte–macrophage cells limits LAV production to primary porcine macrophage cultures, creating constraints in scalability, donor variability, labor, and biosecurity (Auer *et al*., 2024; Chuong *et al*., 2025). Immortalized or permissive cell lines may reduce variability and improve production (Zhang *et al*., 2023).

Scale-up requires optimization of production processes, although infrastructure and supply limitations remain significant (Chuong *et al*., 2025; Diep *et al*., 2025). For nanoparticle vaccines, large-scale production also requires optimized recombinant expression, antigen conjugation, and batch quality control (Zhang *et al*., 2025).

Quality control, biosafety, and regulatory frameworks

Genetic stability is fundamental to LAV safety because mutations or recombination may restore virulence or alter antigenicity. NGS supports monitoring of seed stocks, production batches, and emerging microvariants (Chen *et al*., 2020; Bui *et al*., 2025; Nguyen *et al*., 2025; O'Dwyer *et al*., 2025). Production requires validated aseptic procedures, BSL-3-compliant GMP facilities, and quality assurance of attenuation, potency, and storage stability (Auer *et al*., 2024; WOAH, 2023; Zhang *et al*., 2023).

Regulatory evaluation focuses on safety, immunogenicity, efficacy, and manufacturing quality. LAV candidates require testing in diverse animal populations, including pregnant sows, with continued stage-specific monitoring (Chen *et al*., 2020; Diep *et al*., 2025; Choi *et al*., 2025; Lee *et al*., 2025). DIVA strategies based on gene deletions and companion diagnostics are increasingly required, although fragmented regulatory systems and strain-dependent vaccine performance continue to complicate approval and deployment (Gladue & Borca, 2022; Auer *et al*., 2024; WOAH, 2023; Diep *et al*., 2024; Borca *et al*., 2025).

Pharmacovigilance and future directions

Post-licensure pharmacovigilance remains essential for LAVs. Continuous surveillance incorporating genomic sequencing, adverse-event reporting, and centralized data systems supports early detection of vaccine-derived or recombinant variants (Vu & McVey, 2024).

Vietnam has implemented a supervised deployment framework integrating real-time reporting, genomic surveillance, and centralized data management (Diep *et al*., 2025; Nguyen *et al*., 2025). Large-scale deployment has also strengthened standardized reporting and rapid response systems (WOAH, 2023).

Persistent constraints include reliance on primary cell cultures, limited scalable production platforms, genetic instability, contamination risks, fragmented regulation, and underdeveloped pharmacovigilance systems (Auer *et al*., 2024; Diep *et al*., 2025). Addressing these challenges requires improved production systems, continuous genomic monitoring, regulatory harmonization, and integrated safety frameworks. Emerging platforms, including mRNA and nanoparticle vaccines, together with international collaboration, remain important directions for safer and more scalable ASF vaccine development (Zhang *et al*., 2023; Sunwoo *et al*., 2024; Zhang *et al*., 2024; Auer *et al*., 2024).

Field Deployment and System-Level Barriers

ASF vaccination success depends not only on trial efficacy but also on field realities where biological, logistical, and socioeconomic factors intersect. Strategies must reflect herd structure, farm type, management, and community engagement (Auer *et al*., 2024; Nguyen *et al*., 2025). Addressing these determinants is essential for sustainable ASF control (Gladue & Borca, 2022; WOAH, 2023). Regional variation further necessitates tailored deployment and monitoring strategies (Bui *et al*., 2025).

Vaccination Strategies and Production Context

Vaccination protocols should align with production stage and herd characteristics. Protection of breeding animals is critical, although late-gestation vaccination requires careful scheduling (Diep *et al*., 2025; Choi *et al*., 2025; Lee *et al*., 2025). For fatteners, rapid protection is essential because of the short production cycle. Prime–boost regimens enhance both humoral and cellular immunity, improving the durability and breadth of protection (Diep *et al*., 2025; Nguyen *et al*., 2025).

Nevertheless, genotype II LAVs show strain-dependent efficacy, while maternal immunity and emerging microvariants complicate vaccination schedules (O'Dwyer *et al*., 2025; Zhang *et al*., 2023). Vaccination should therefore be coordinated with key production stages to minimize immunity gaps, and intradermal delivery may further enhance $CD8^+$ memory responses (Pedrera *et al*., 2024).

Production systems also influence vaccine performance. Smallholder farms often face limitations in biosecurity, veterinary access, and compliance, whereas commercial farms benefit from standardized vaccination but remain vulnerable because of high stocking density (Auer *et al*., 2024; Gladue & Borca, 2022; WOAH, 2023; MARD, 2023). Vietnam's experience further highlights the need for system-specific monitoring (Nguyen *et al*., 2025).

Socioeconomic, Operational, and Biosecurity Constraints

Farmer acceptance, surveillance capacity, and regulatory compliance remain critical determinants of vaccine uptake (Auer *et al*., 2024; Bui *et al*., 2025; MARD, 2023; Chuong *et al*., 2025).

Vaccination should be integrated with broader biosecurity strategies, including vaccinate-to-live, stamping-out, or hybrid approaches selected according to epidemiological risk and supported by molecular surveillance (Auer *et al*., 2024; WOAH, 2023; Diep *et al*., 2024; Borca *et al*., 2025).

Operational barriers—including cold-chain requirements, workforce limitations, and monitoring capacity—continue to constrain implementation, particularly in resource-limited settings. Strengthening infrastructure, veterinary capacity, and digital monitoring systems can improve deployment and oversight (WOAH, 2023; MARD, 2023; Chuong *et al*., 2025; Diep *et al*., 2025).

Sustainable ASF control requires governance frameworks that integrate vaccination with production systems, surveillance, and biosecurity. Success depends on stakeholder engagement, standardized protocols, regulatory oversight, and coordinated pharmacovigilance. Vietnam's experience demonstrates the value of integrating traceability, surveillance, and field monitoring into large-scale deployment, while international collaboration remains essential for harmonized regulation, technology transfer, and capacity building (MARD, 2023; WOAH, 2023; Chuong *et al*., 2025; Diep *et al*., 2025).

Case Study: Vietnam’s Supervised Deployment Experience

Vietnam was the first country to authorize and implement ASF LAVs under supervised field conditions (WOAH, 2023). Recent literature identifies this deployment as the most comprehensive real-world assessment of ASF LAV performance, reflecting Vietnam’s capacity to integrate regulatory, financial, and monitoring systems to ensure safety and efficacy (Ngo *et al*., 2026; MARD, 2023).

Regional Context and Strategic Coordination

Since 2019, ASF has become endemic across Southeast Asia, disrupting pork supply

chains in multiple countries including Vietnam, the Philippines, Laos, Cambodia, Myanmar, and China (Auer *et al*., 2024; Chuong *et al*., 2025). Persistent circulation in both domestic and wild pig populations, combined with complex spatiotemporal transmission dynamics, continues to complicate eradication efforts (Bui *et al*., 2025). These conditions necessitate coordinated regional strategies, including harmonized regulatory frameworks, synchronized vaccine deployment, and shared surveillance systems (Gladue & Borca, 2022; Auer *et al*., 2024).

National Implementation and Policy Innovation

Vietnam has taken a leading role in ASF vaccine deployment, licensing two LAVs—AVAC ASF LIVE and NAVET-ASFVAC—since 2022 (WOAH, 2023). Field trials and post-deployment surveillance have demonstrated efficacy rates of 90-100% with adverse events below 1% (Tran *et al*., 2022; WOAH, 2023; Diep *et al*., 2025). Nearly four million doses have been administered across more than 140 farms in 22 provinces, representing the largest controlled field evaluation globally. Vaccination has contributed to substantial reductions in outbreak frequency and mortality, with some provinces reporting declines exceeding 60%, although these outcomes also underscore the need for sustained surveillance and careful LAV management (Nguyen *et al*., 2025).

Vaccination has been formally integrated into Vietnam's National ASF Control Plan (2025–2030), which includes the establishment of biosecure livestock zones, mandatory vaccination in high-risk provinces, and targeted subsidies for smallholder farmers (MARD, 2023). This integration stabilizes implementation, expands coverage, and aligns disease control with broader agricultural development priorities, particularly given the significant economic burden of ASF (Acosta *et al*., 2023).

Policy and governance innovations have played a central role in enabling this deployment. Conditional licensing frameworks allowed accelerated approval during outbreaks while maintaining oversight through staged rollout, real-time reporting, and periodic regulatory review. Financial mechanisms, including tiered subsidies and livestock insurance schemes linked to vaccination compliance, improved accessibility and incentivize uptake. In parallel, digital traceability systems—such as QR-coded vaccine batches linked to centralized databases—enabled rapid detection of adverse events, quality assurance, and improved market transparency. Continuous feedback between field data and policy enabled refinement of vaccination schedules and deployment logistics (Tran *et al*., 2022; Diep *et al*., 2025).

Regional Surveillance and Translational Implications

Despite progress, ASF surveillance across Southeast Asia remains fragmented (Bui *et al*., 2025). In this context, Vietnam provides a representative model of large-scale vaccine deployment under endemic conditions, offering practical insights into surveillance, pharmacovigilance, and risk management. A coordinated regional network is required to systematically monitor vaccine performance, adverse events, and viral evolution (WOAH, 2023).

Variation in vaccine efficacy across circulating ASFV strains further highlights the need for regionally adapted strategies. Priority directions include the development of recombinant LAVs with engineered deletions to enhance safety (Chen *et al*., 2020; Liu *et al*., 2023; Sunwoo *et al*., 2024); expansion of multicenter trials and harmonized regulatory frameworks (WOAH, 2023; Diep *et al*., 2024); the establishment of regional manufacturing hubs to reduce import dependence (Zhang *et al*., 2023); and integration of vaccinations within strengthened biosecurity and surveillance systems (Auer *et al*., 2024; O'Dwyer *et al*., 2025).

In Vietnam, integrated QR-code traceability, pharmacovigilance, and genomic surveillance support monitoring of vaccine performance and viral evolution. Strain-dependent vaccine performance further supports context-specific deployment strategies (Borca *et al*., 2025). In addition, gestation-stage–specific vaccination protocols demonstrate feasibility in breeding herds, reinforcing the role of controlled,

evidence-based integration of LAVs into reproductive management (Choi *et al*., 2025; Lee *et al*., 2025).

Overall, Vietnam's experience demonstrates that ASF vaccination must operate within an integrated framework of governance, surveillance, and innovation. This model not only enables effective national control but also provides a scalable template for regional coordination and global ASF management.

Future Orientations and Research Priorities

Despite progress in African swine fever (ASF) vaccine development, scientific, regulatory, and logistical barriers still impede safe and effective deployment. Live attenuated vaccines (LAVs), though highly immunogenic, raise concerns regarding biosafety, reversion, and trade acceptance (Gladue & Borca, 2022). Strengthening ASF control requires advancements in next-generation platforms, intensified collaborations, and integration of vaccinations into coordinated national and regional strategies.

Next-Generation Vaccine Platforms and Hybrid Strategies

ASF vaccine development must diversify beyond LAVs. While LAVs provide durable immunity, residual virulence and incompatibility with DIVA strategies necessitate alternative approaches (Chu *et al*., 2024; Diep *et al*., 2024; Nguyen *et al*., 2025). The emergence of ASFV microvariants in the Asia–Pacific region further reinforces the need for adaptable and precision-based platforms (O'Dwyer *et al*., 2025).

Gene-edited LAVs represent a key transitional strategy. CRISPR/Cas-based deletions can attenuate virulence while preserving immunogenicity (Sunwoo *et al*., 2024; Borca *et al*., 2025). Advances in recombination-based engineering emphasize the importance of pre-licensure testing in pregnant sows, extended follow-up, and genomic quality control to detect delayed effects or recombination events (Vu & McVey, 2024). Targets such as I73R enable rational attenuation (Liu *et al*., 2023), while multi-gene deletions (e.g., ASFV-G-ΔI177L/ΔLVR) enhance safety in breeding herds and sustain protective immunity (Lee *et al*., 2025; Choi *et al*., 2025). These approaches build on earlier evidence demonstrating protection against Vietnamese field strains using I177L-deleted constructs (Tran *et al*., 2022), although continuous genomic surveillance remains essential (Nguyen *et al*., 2025).

mRNA vaccines offer scalable and biosafe alternatives, enabling controlled antigen expression and DIVA-compatible designs. Constructs encoding conserved proteins such as p72 and p54 have demonstrated induction of both humoral and cellular immunity in preclinical studies (Zhang *et al*., 2023; Sunwoo *et al*., 2024). However, cold-chain requirements and dependence on lipid nanoparticle delivery systems remain significant constraints in resource-limited settings (Auer *et al*., 2024). These platforms are therefore particularly suited for booster roles within hybrid vaccination strategies.

Nanoparticle-based vaccines further expand this landscape by enhancing antigen stability, dendritic-cell targeting, and lymphoid delivery. These systems promote robust $CD8^+$ responses, germinal-center reactions, and mucosal immunity, while remaining compatible with DIVA strategies (Zhang *et al*., 2023; Pedrera *et al*., 2024). Recent studies have demonstrated that engineered nanoparticle constructs, including encapsulin-conjugated p54, can induce Tfh and germinal-center B-cell responses alongside broad neutralization across ASFV variants (Zhang *et al.*, 2025; Lee *et al.*, 2026). These findings support their evaluation as both booster and potentially standalone platforms in next-generation vaccine design.

Hybrid approaches integrating LAV priming with mRNA or nanoparticle boosting represent a promising direction. Such strategies combine the strong cellular immunity of LAVs with the safety and precision of engineered platforms, potentially overcoming limitations in cross-genotype protection (Diep *et al*., 2024; Sunwoo *et al*., 2024; Zhang *et al*., 2024). Embedding these platforms into national portfolios, supported by technology transfer and regional

production, will be essential for scalable implementation, particularly in low- and middle-income countries (Auer *et al*., 2024).

Collaboration, Technology Transfer, and Regional Leadership

ASFV's biological complexity necessitates interdisciplinary collaboration across immunology, virology, genomics, and bioengineering. Research priorities include T-cell epitope mapping, adjuvant optimization, replication kinetics, and the identification of virulence determinants (Auer *et al*., 2024), alongside advanced epidemiological modeling and coordinated surveillance (Bui *et al*., 2025).

Global data sharing plays a central role in this effort. Transparent exchange of genomic and epidemiological data supports real-time tracking of viral evolution and informs vaccine design. Platforms coordinated by WOAH facilitate outbreak mapping, genomic surveillance, and post-vaccination monitoring, underscoring the importance of integrated global surveillance systems (WOAH, 2023; Nguyen *et al*., 2025).

Technology transfer remains a critical bottleneck, particularly in regions lacking BSL-3 infrastructure. Public–private partnerships, international funding mechanisms, and regional training initiatives are required to expand research and production capacity (Gladue & Borca, 2022; Auer *et al*., 2024). Equitable access to technology not only reduces duplication but also strengthens local manufacturing capabilities and long-term resilience (WOAH, 2023; Bui *et al*., 2025), which are essential given the substantial economic burden of ASF (Acosta *et al*., 2023).

Vietnam's supervised deployment of NAVET-ASFVAC and AVAC ASF LIVE provides a valuable case study for global ASF vaccine implementation. Conditional licensing combined with large-scale, controlled field rollout represents one of the most comprehensive evaluations to date (MARD, 2023; WOAH, 2023). The reported high efficacy and reductions in recurrence demonstrate the feasibility of regulated LAV deployment under strong governance (Diep *et al*., 2025).

Beyond national impact, Vietnam is uniquely positioned to contribute to multicenter trials, immunological profiling, and regional comparative studies. Transparent sharing of genomic and safety data, particularly regarding vaccine-derived or recombinant variants, strengthens early warning systems and regional preparedness (Diep *et al*., 2025). These experiences position Vietnam as both a testbed and a catalyst for coordinated ASF vaccine governance across endemic regions.

Manufacturing, Scale-Up, and Sustainable Governance

Scaling ASF vaccine production remains a major constraint, particularly for LAVs that depend on porcine macrophages or specialized cell lines (Gladue & Borca, 2022). These limitations affect production throughput, consistency, biosafety, and cost (Auer *et al*., 2024; Chuong *et al*., 2025).

Advanced bioprocessing technologies, including continuous bioreactor systems, offer solutions by stabilizing cell density, optimizing viral yield, and enabling real-time monitoring. Integration with next-generation sequencing allows early detection of genetic drift, mutations, or contamination, thereby improving safety and quality assurance (Zhang *et al*., 2023; Borca *et al*., 2025). Standardized quality control frameworks—including genomic verification, contaminant screening, immunogenicity confirmation, and DIVA marker integration—are essential for regulatory acceptance and large-scale deployment (WOAH, 2023). Regional harmonization of regulatory standards can further accelerate licensing and reduce duplication (Auer *et al*., 2024).

Long-term ASF control also depends on sustainable financing and governance models. Many endemic regions face limitations in veterinary infrastructure, supply chains, and vaccine accessibility (Auer *et al*., 2024). Collaborative frameworks involving governments, industry, and international organizations can pool resources, distribute risk, and support innovation. Blended financing mechanisms—combining public subsidies with

private-sector participation—help sustain affordability while incentivizing development.

Risk-sharing tools, including insurance schemes and contingency funds, can buffer economic losses and promote vaccine uptake (MARD, 2023). Vietnam's tiered subsidy model provides a practical example of equitable implementation. Effective governance further requires transparent regulatory frameworks, stakeholder engagement, and integration of surveillance with post-vaccination monitoring to support adaptive, evidence-based policies (Chuong *et al*., 2025; Diep *et al*., 2025).

Conclusions and Recommendations

Summary of Progress and Remaining Challenges

ASF remains one of the most complex and economically disruptive transboundary diseases, with Southeast Asia bearing a disproportionate burden. Despite major advances—most notably Vietnam's conditional licensing and supervised deployment of LAVs—scientific, regulatory, and logistical barriers continue to hinder sustainable control.

ASF continues to destabilize swine production systems, threatening food security, rural livelihoods, and regional markets. Its economic toll has intensified food insecurity across Asia. Vietnam's commercialization of locally adapted LAVs demonstrates that supervised vaccine deployment can achieve high protection, reduce mortality, and support market stabilization.

However, key challenges persist. The emergence of vaccine-derived or recombinant variants highlights the risks of virulence reversion and recombination. The absence of robust, field-validated DIVA-compatible diagnostic systems continues to limit surveillance, traceability, and differentiation between infected and vaccinated animals (González-García *et al*., 2025). While progress has been made, variability in assay sensitivity across ASFV genotypes and field conditions constrains large-scale implementation. Variable protection across genetically diverse ASFV strains underscores the need for multivalent or hybrid approaches, while the continued evolution of ASFV variants in the Asia–Pacific region complicates immunity and vaccine performance.

Strategic Recommendations for Vietnam and the Region

Next-generation platforms—including mRNA, nanoparticle, and vector-based vaccines—offer important advantages in safety, scalability, and antigenic precision. However, practical constraints remain, including cold-chain requirements for mRNA vaccines and the technical complexity of nanoparticle production.

A risk-managed hybrid model is recommended for Vietnam and neighboring countries. This approach integrates gene-edited LAVs for broad immunization in endemic areas, combined with next-generation boosters to enhance durability, breadth, and DIVA compatibility. Program design should be tailored to herd structures and production systems. Staged field trials, supported by genomic surveillance and DIVA-integrated platforms, are critical to ensure safety and effectiveness prior to large-scale deployment.

Effective ASF control further requires harmonized and transparent governance. Strengthened regulatory frameworks should ensure approval standards, traceability, and post-market pharmacovigilance. Farmer communication, training, and community engagement must be institutionalized to sustain compliance. Regional cooperation will be essential to harmonize regulatory standards, coordinate vaccine deployment, and monitor cross-border viral movement. Continuous genomic surveillance will also be critical to detect emerging variants and guide adaptive immunization strategies.

Outlook: Integrating Innovation, Governance, and Sustainability

Effective ASF vaccine deployment must integrate scientific innovation with coherent policies, stakeholder engagement, and international collaboration. Vietnam's rapid adoption of LAVs demonstrates both opportunity and risk, offering a practical model for risk-managed implementation.

Sustained innovation, supported by strong governance and transparent regulation, will be crucial for long-term success. Continued investment in research and development, modernized regulatory systems, and technology transfer is needed to translate laboratory advances into safe and accessible vaccines at scale. Expanding production through advanced bioprocessing technologies will help meet increasing demand while maintaining quality assurance.

Global experiences have revealed uneven detection and response capacities, underscoring the need for harmonized surveillance and capacity building. Future vaccine strategies should prioritize broader immunogenic coverage, including multivalent or region-specific designs. While gene-deleted LAV platforms remain a central reference for effective attenuation, next-generation approaches—particularly nanoparticle-based vaccines with a programmable antigen display and enhanced immune targeting—are emerging as viable candidates for safer, DIVA-compatible, and scalable immunization strategies (Lee *et al*., 2026). Monitoring of potential immune-mediated risks, including ADE, should be incorporated into pre-licensure evaluation frameworks.

Sustainable ASF control ultimately depends on aligning next-generation science with practical governance and socio-economic realities. Regional cooperation, financial support mechanisms, and coordinated regulatory oversight will underpin equitable vaccine access and long-term resilience in the swine sector. Vietnam's experience illustrates how biosafety, regulation, and stakeholder engagement can be integrated into scalable national programs.

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