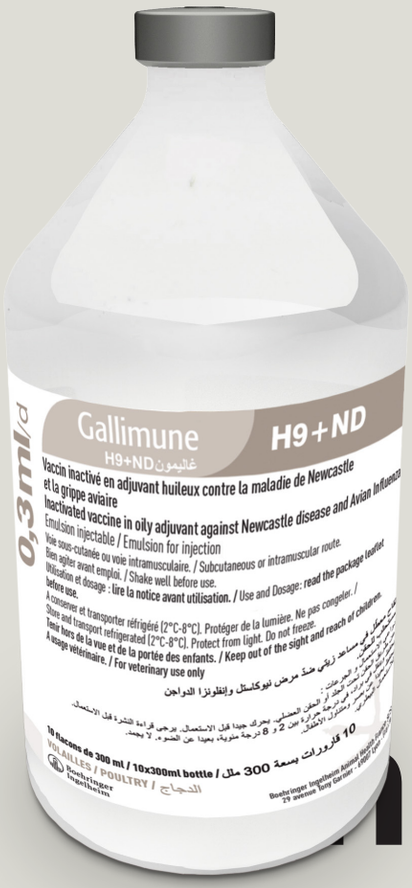
Winning against Avian Influenza H9N2?



It is possible.

With GALLIMUNE® H9+ND

Bivalent inactivated vaccine providing unmatched protection against AI H9 and Newcastle disease field viruses.

Unrivaled efficacy:

- Strong protection against Clinical signs, mortality, and viral shedding[10, 11, 12, 13]
- Preservation of growth in case of infection[10]

Wide protection:

- Proven efficacy against Middle East, African and Asian H9N2 isolates[6,8]

Hatchery or farm administration:

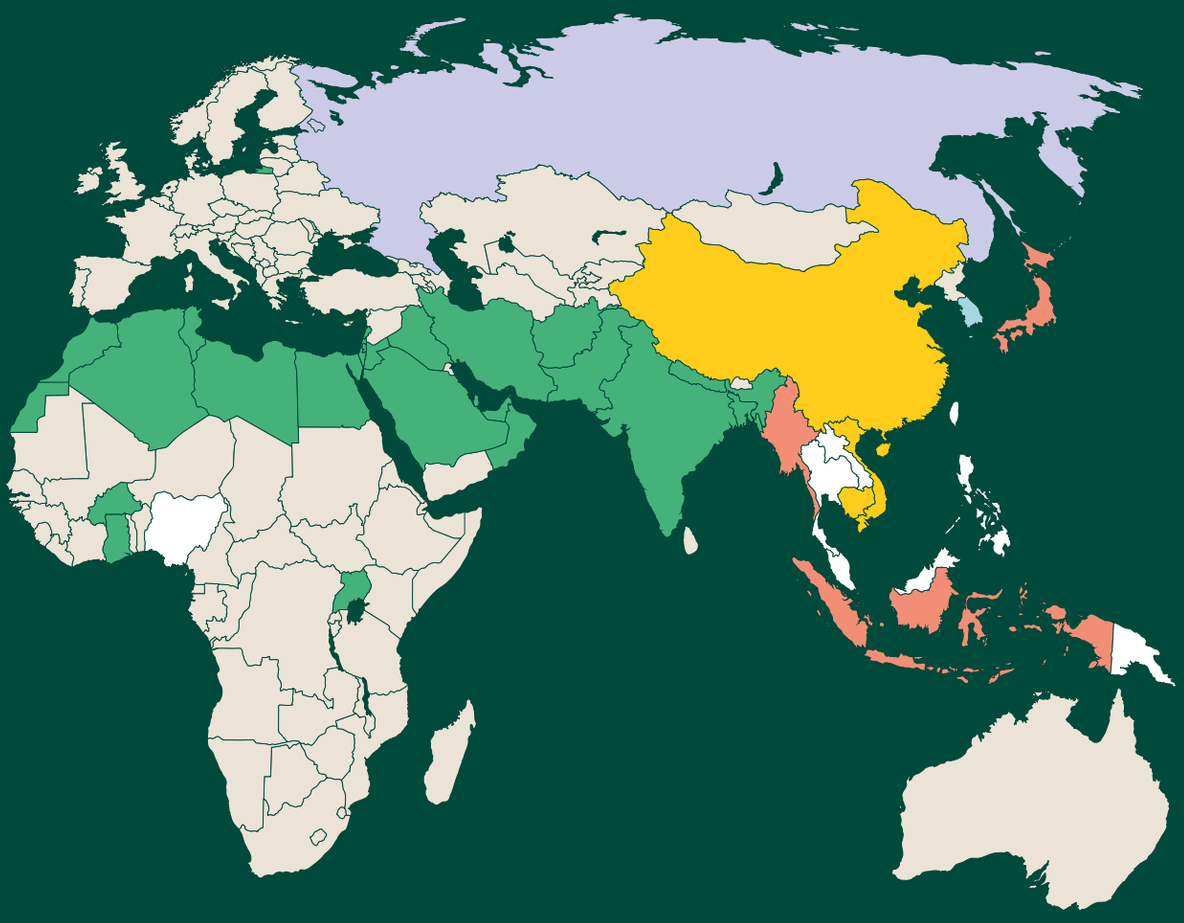
- Safe and highly syringeable[14]
- Concomitant injection with VAXXITEK[15]
- Available in monovalent or combined formulation

Boehringer Ingelheim

Avian Influenza Subtype H9

Avian influenza (AI) is a disease caused by type A influenza virus strains. The viruses cause a variety of clinical symptoms and significant losses to poultry operations worldwide. Influenza A viruses are classified in different subtypes based on differences in their surface proteins, the hemagglutinin (HA) and neuraminidase (NA).

Geographic distribution of poultry-adapted H9N2 virus isolates[1]



[1] *Adapted Peacock et al, A Global Perspective on H9N2 Avian Influenza Virus, Viruses, 11(7):620, 2019*

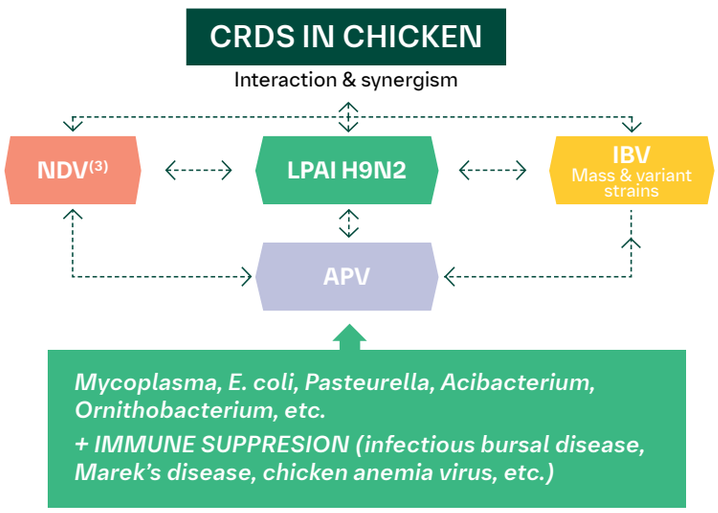
LPAI H9N2: frequently involved in the complex respiratory disease syndrome (CRDS)[2,3]

Low pathogenic H9N2 AIV is one of the major concerns of poultry production in many regions around the world. Although H9N2 is a virus of low pathogenicity (LPAI), it is a critical factor in the complex respiratory disease frequently associated in field conditions with enhanced morbidity, mortality and drops in egg production. The most common clinical signs are depression (reduced appetite, ruffled feathers, inactivity), respiratory signs (sneezing, coughing, sinusitis, tracheitis), swollen head, increased susceptibility to secondary diseases and decreased performance.

Since 1999, an increasing number of poultry farms in the Middle East, Northern Africa, and more recently Central Asia, are facing very severe outbreaks of a new Complex Respiratory Disease Syndrome (CRDS), characterized by very high mortality and severe drops in egg production. With the aid of domestic diagnostic laboratories, the Boehringer Ingelheim Technical Service team has been able to identify that this new CRDS almost always involves:

- **A Low Pathogenicity Avian Influenza virus subtype H9N2 (alone, this low pathogenicity AI subtype does not usually provoke severe symptoms)**
- **Other respiratory viruses (velogenic Newcastle Disease virus clearly being the most dangerous)**
- **Immunosuppressive factors**
- **Various bacteria and mycoplasmas**

The CRDS is also frequenlty compounded by management failures.



[2] Gowthaman V, Singh SD, Dhama K, Srinivasan P, Saravanan S, Gopala Krishna Murthy TR, Ramakrishnan MA. Molecular Survey of Respiratory and Immunosuppressive Pathogens Associated with Low Pathogenic Avian Influenza H9N2 Subtype and Virulent Newcastle Disease Viruses in Commercial Chicken Flocks. J Poult Sci. 2017

[3] Bonfonte et Al. Synergy or interference of a H9N2 avian influenza virus with a velogenic Newcastle Disease virus in chickens are dose dependent, Avian Pathology}, Volume 46, 488 - 496, 201711(7):620, 2019

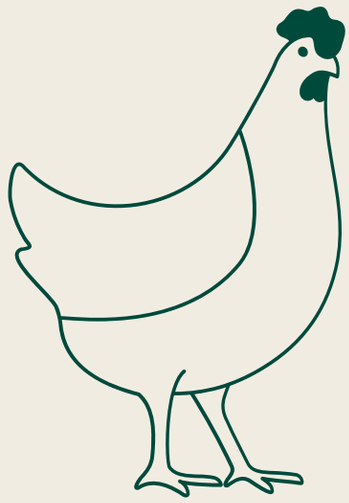
Newcastle disease[4]:

A highly contagious, potentially devastating disease.

Newcastle Disease (ND) is a worldwide disease in chickens caused by the avian paramyxovirus serotype 1 (APMV-1), a single-stranded RNA virus that can cause devastating losses to the poultry industry. Newcastle Disease has different degrees of pathogenicity: it can be apathogenic (lentogenic forms), moderately pathogenic (mesogenic forms) or highly pathogenic (velogenic forms).

The most virulent form of the disease can cause up to 100% mortality and the main clinical signs are respiratory signs, depression, watery greenish diarrhea and head swelling. Young birds are the most susceptible to this form. Laying hens might experience partial or complete cessation of egg production, and eggs can be abnormal in color, shape, surface or have watery albumen.

Given the high contagiousness of Newcastle Disease, once the virus is introduced into a susceptible flock, virtually all the birds will be infected within two to six days. Since no real treatment exists, it's fundamental to provide the birds with a reliable clinical protection through a safe and effective vaccine.



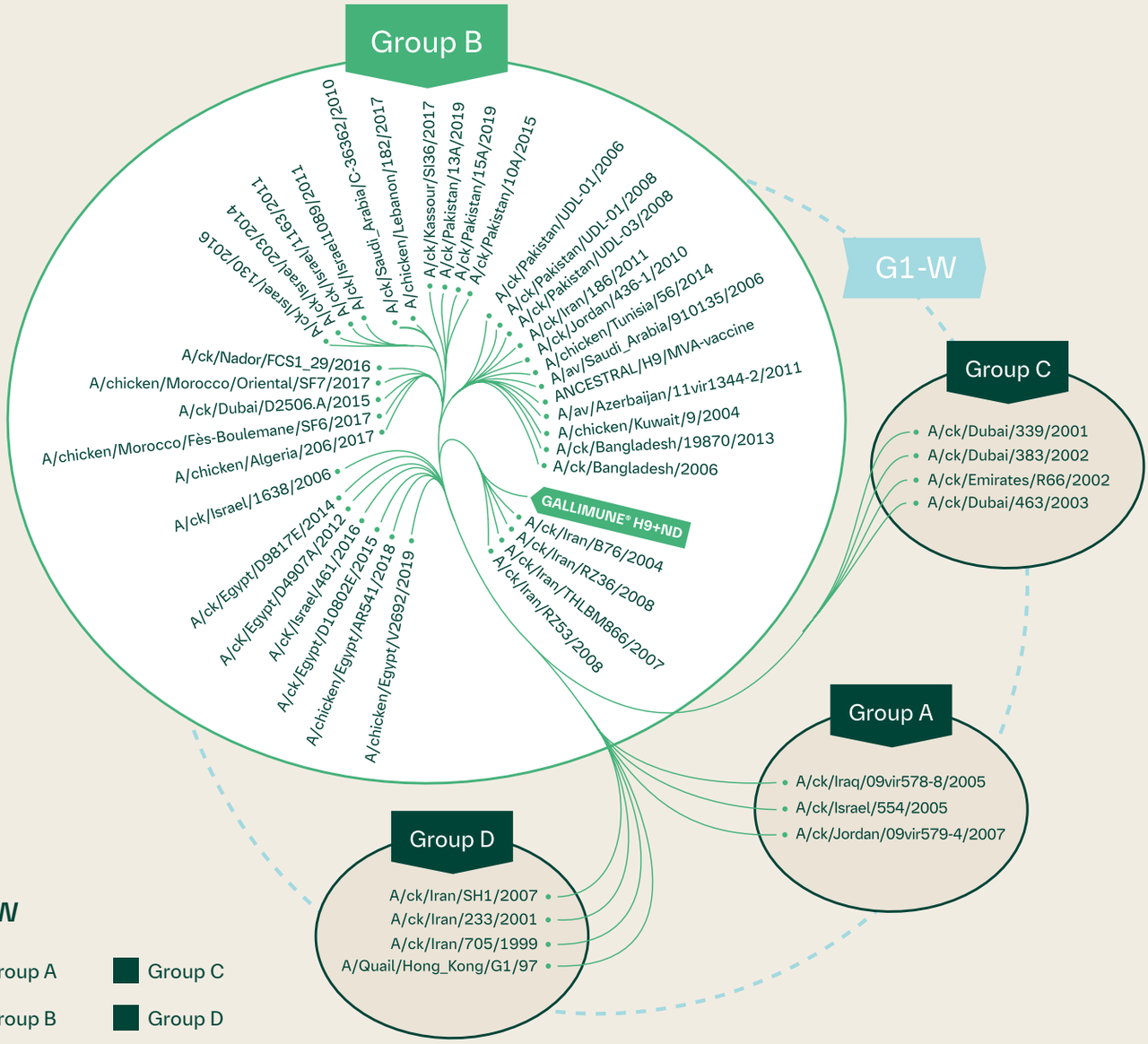
[4] Ganar K, Das M, Sinha S, Kumar S. Newcastle disease virus: current status and our understanding. Virus Res. 2014

GALLIMUNE® H9+ND: a significantly increas to support the profitability of your flocks

At Boehringer Ingelheim, we understand that you need continuous innovation to keep protecting birds.

The GALLIMUNE® H9+ND is a highly efficient vaccine that reduces the clinical signs and the mortality related to H9N2 infections.

Thanks to its selected H9N2 AI strain, GALLIMUNE® H9+ND contains an AIV virus strain with a carefully selected broadly matching H9 antigen of the group B of the G1-W lineage. The Group B is currently the most prevalent circulating group within Middle-East and North Africa regions[5].



[5]*Fusaro A. et Al., Phylogeography and evolutionary history of reassortant H9N2 viruses with potential human health implications. J Virol., 85(16):8413-21, 2011*

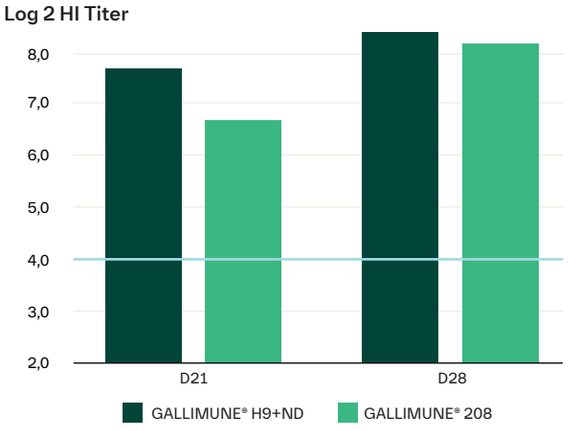
ed protection against H9N2[5] infections

With GALLIMUNE® H9+ND you raise the protection level of your flocks to win against Avian Influenza H9N2.

The GALLIMUNE® H9+ND fosters a significantly increased seroconversion based on hemagglutination inhibition assay (HI) when compared to the GALLIMUNE® 208 ND+FluH9 M.E. in both Specifc Pathogen Free (S.P.F.) chickens and conventional broilers.[6]

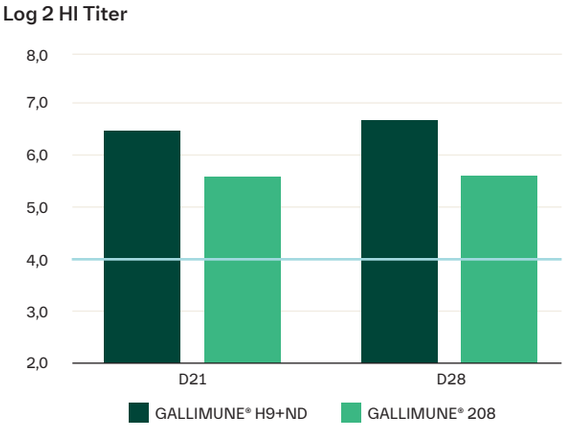
In S.P.F. chickens

The potency of the GALLIMUNE® 208 and GALLIMUNE® H9+ND was evaluated at D21 and D28 on S.P.F. birds vaccinated at one day old via subcutaneous route. Immune response was assessed by HI using 15 different H9N2 strains originated from Middle-East area as antigens. HI Serology shows that both vaccines provide titers above 4log2 positivity threshold[7] at 21 and 28 days post-vaccination. GALLIMUNE® H9+ND provides a higher HI seroconversion at both ages.



In Broilers

The potency of the GALLIMUNE® 208 and GALLIMUNE® H9+ND was also evaluated at D28 and D35 on broilers vaccinated at D7 using HI with the same 15 antigens. The serology in conventional broilers confirms the results obtained in S.P.F. birds with higher titers in GALLIMUNE® H9+ND groups at 21 and 28 days post-vaccination.



Newly tested against 6 recent H9N2 strains from African, Middle Eastern, and Asian regions with fast and strong seroconversion at 21 days post vaccination using GALLIMUNE® H9+ND[8].

GALLIMUNE® H9+ND enhances the protection level against challenges posed by circulating field viruses with increased virulence.

[6] *Herrmann A. et Al., 2020, AAAP Symposium, San Diego, USA*

[7] *OIE Terrestrial manual 2021*

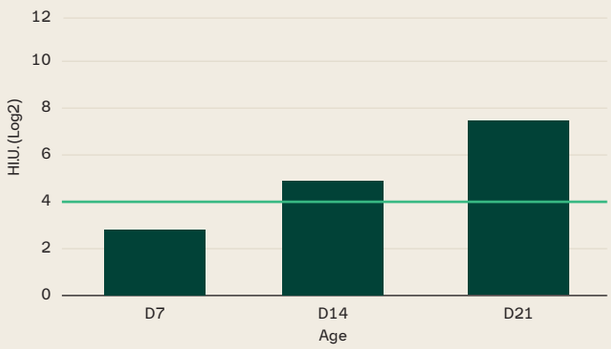
[8] *Fellahi et al., Comparison of the protection conferred by different inactivated vaccines against low pathogenic avian influenza H9 following a homologous challenge with an H9N2 strain isolated in Morocco, 2024, data on File.*

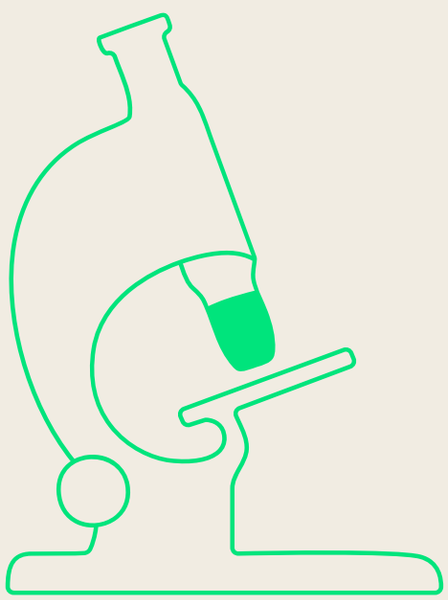
Strong protection with improved flock perfo

Early onset of immunity[9]

A Boehringer Ingelheim study on the serological efficacy of GALLIMUNE® H9+ND to evaluate the onset of immunity (OOI) showed that 45 day-old SPF chicks were vaccinated with 0.2 ml of GALLIMUNE® H9+ND by subcutaneous route. The OOI was evaluated by monitoring the seroconversion and evaluating the fulfillment of the OIE Avian Influenza requirements (titres > 4 log2 HIU). The H9N2 serological results showed a **start of seroconvertion from 7 days of age**, an average H9N2 mean titer already higher than 4Log2 at 14 days of age, and a high seroconversion against H9N2 at 21 days of age (>7 Log2).

Average H9N2 titers

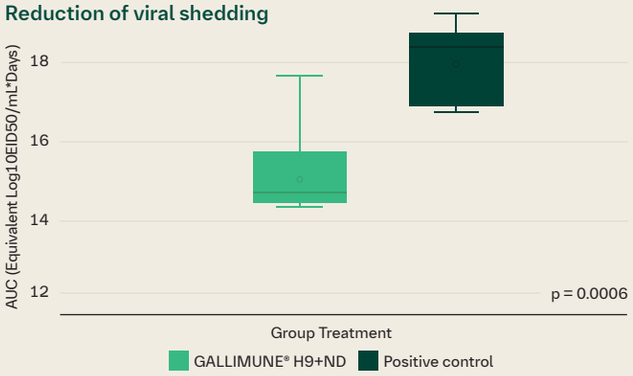




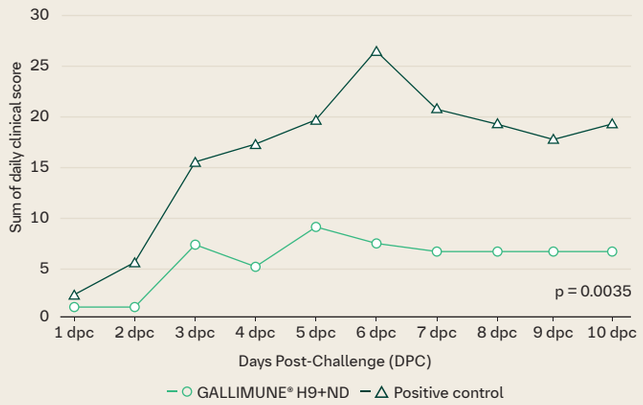
Efficacy in conventional broilers[10]

A Boehringer Ingelheim study on clinical protection of GALLIMUNE® H9+ND against H9N2 of Middle East challenge model using the H9N2 virus alone was conducted in order to evaluate clinical signs post challenge, viral shedding and body weight gain in commercial broiler chickens. In the performed clinical trial[12], the birds were challenged at 21 days of age and inoculated with a H9N2 virus isolated in Saudi Arabia in 2010 at the dose of 10^9 EID50. The trial showed **significant decrease in terms of clinical score, viral shedding and increase of body weight gain** compared to the positive control (challenged and not vaccinated group).

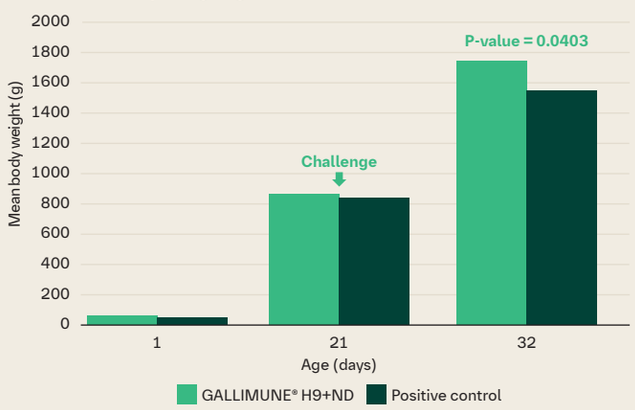
Reduction of viral shedding



Reduction of respiratory clinical signs



Preserved body weight gain



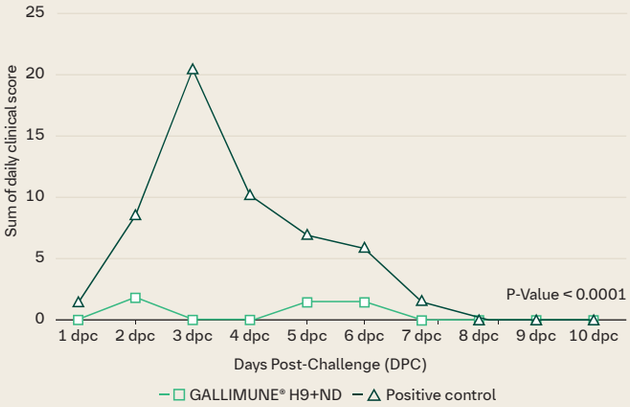
rmances[9, 10, 11]

Efficacy in conventional layers[11]

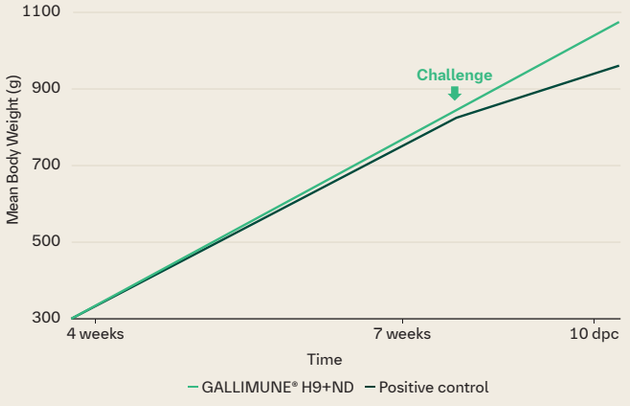
A Boehringer Ingelheim study on clinical protection of GALLIMUNE® H9+ND against H9N2 of Middle East challenge model using the H9N2 virus alone was conducted in order to evaluate clinical signs post challenge and body weight gain in 4-weeks-old conventional layer pullets ISA Brown. In the performed clinical trial, the birds were challenged 21 days post vaccination (7 weeks of age) and inoculated with a H9N2 virus isolated in Saudi Arabia in 2010 at the dose of 10^9 EID50.

The trial showed a **significant reduction of clinical signs including no loss of body weight gain after the challenge.**

Reduction of respiratory clinical signs



Preserved body weight gain



[9]Study 20200487, Boehringer-Ingeheim, 2020
[10]Study 17.0376.R, Boehringer-Ingeheim, 2017
[11]Study 18.0082.R, Boehringer-Ingeheim, 2018

[12] Zhari A, Rawi T, Arbani O, Delvecchio A, Herrmann A, Kichou F, Drissi Touzani C, Ducatez MF, Fellahi S. Assessment and comparison of immunogenicity and protective efficacy of inactivated and vectored vaccines against Moroccan H9N2 avian influenza virus challenge in broiler chickens with maternally derived antibodies. Avian Diseases (under review, manuscript ID: avian diseases-D-25-00012). 2025.

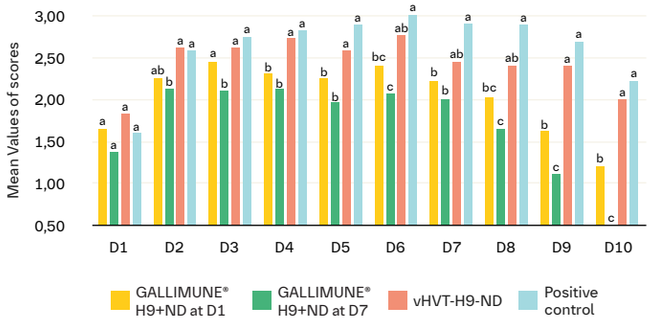
Comparison with commercial vHVT-ND-H9[12]

A study was performed to assess the protection conferred by GALLIMUNE® H9+ND administered at day old and 7 days of age and a commercially available vector ND H9 vaccine (vHVT+ND+H9) administered at day old when challenged at 28 DOA with a LPAI H9N2.

The study showed mortality only in the vHVT+ND+H9 group due to respiratory issues (7%). Viral shedding was reduced and shorter in duration in GALLIMUNE® H9+ND groups compared to the vHVT+ND+H9 group. Viral clearance was achieved by day 8 with the GALLIMUNE® H9+ND group whilst the vHVT+ND+H9 group still excreted.

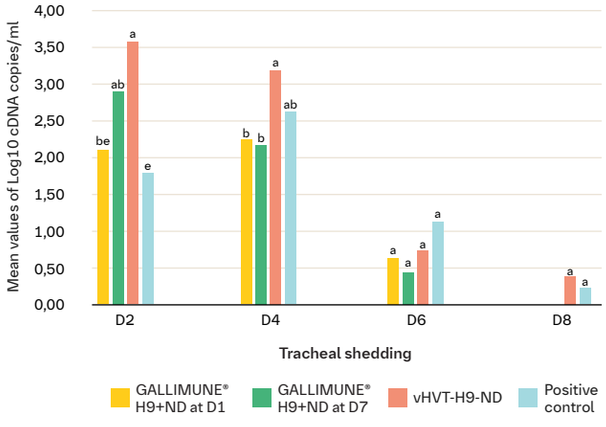
GALLIMUNE® H9+ND at D1 or D7 provides a **stronger protection against H9 challenge when compared to HVT ND H9 based on mortality, clinical and lesion scoring and shedding.**

Reduction of respiratory clinical signs



Different letters assigned to each observed lesion indicate a significant difference (P < 0.05).

Reduced and shorter viral shedding

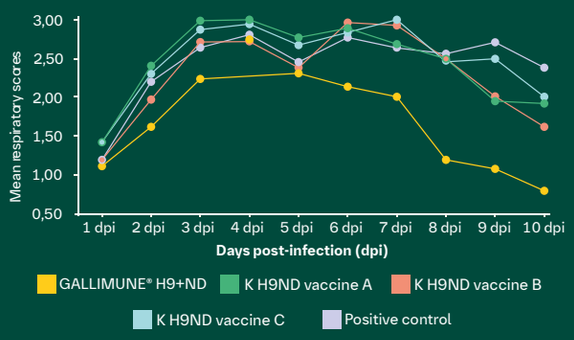


Comparison with commercial killed vaccines[13]

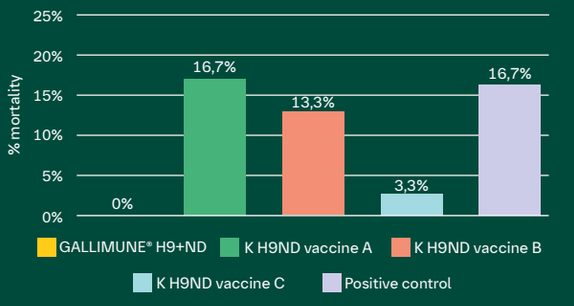
A study on four inactivated vaccines was conducted to evaluate the efficacy against H9N2 in commercial broiler chickens at 28 days of age. The study's results revealed significant differences in the clinical symptoms exhibited by the challenged groups. The group vaccinated with GALLIMUNE® H9+ND, showed the lowest mean respiratory and ocular scores, indicating a milder disease course and faster recovery compared to the other groups. This group reported no mortality, unlike the other challenged groups. Birds vaccinated with GALLIMUNE® H9+ND consistently exhibited lower numbers of shedders compared to other groups, across all time points throughout the study period.

GALLIMUNE® H9 + ND compared to 3 commercial inactivated vaccines **provided the highest level of protection against H9N2 challenge,** as indicated by reduced clinical signs, lower mortality, stronger immune responses, and reduced viral shedding.

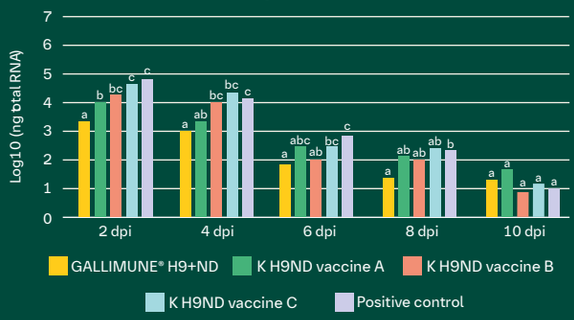
Significative reduction of respiratory symptoms



Prevention of mortality



Reduction of viral shedding



Boehringer Ingelheim

For more adaptability: available in **monovalent** or **combined formulation.**

GALLIMUNE® H9 range of vaccines provides unmatched protection against AI H9 field viruses.

Unrivaled efficacy:

- Strong protection against clinical signs, mortality, and viral shedding[10, 11, 12, 13]
- Preservation of growth in case of infection[10]

Wide Protection:

- Proven efficacy against Middle East, African and Asian H9N2 isolates[6,8]

Hatchery or farm administration:

- Safe and highly syringeable[14]
- Concomitant injection with VAXXITEK®[15]
- Available in monovalent or combined formulation

[13] *Arbani O. Low pathogenic avian influenza H9N2 in Morocco: Epidemio-molecular evolution, pathological and vaccine efficacy assessment against emerging variants (2021–2024) [PhD thesis]. Rabat (Morocco): Agronomy and Veterinary Institute Hassan II; 2025.*

[14] *Study 2004.057, Boehringer-Ingelheim, 2004*

[15] *Study 2004.057, Boehringer-Ingelheim, 2004 Wassah, Theophilus Npopi. Étude expérimentale de la co-infection du virus de la bursite infectieuse aviaire et le virus d'influenza aviaire faiblement pathogène H9N2 chez le poulet de chair. PhD thesis, Agronomy and Veterinary Institute Hassan II, Rabat, Morocco. 2020.*

Life forward