

# Bulletin

Boehringer Ingelheim Vetmedica, Inc.

TECHNICAL

## Multi-site Field Study Confirms Safety of 3FLEX™ Vaccine Mixture

3FLEX™ is the trade name associated with the mixture of Ingelvac CircoFLEX®, Ingelvac MycoFLEX®, and Ingelvac® PRRS MLV swine vaccines. As part of the federal regulatory licensing process and apart from vaccine efficacy studies, field studies were conducted under conditions typical of expected vaccine usage in three different geographic locations to assess the safety of the 3FLEX vaccine mixture.

### Materials & Methods

Healthy, weaned pigs from 18-25 days of age were randomly assigned to one of two treatment groups at the three participating sites (Table 1). Pigs were injected intramuscularly (IM) in the neck with their randomly assigned treatment and treatment groups were commingled during the study. Clinical observers were blinded to treatment, and all pigs were observed for clinical abnormalities and systemic or local (injection site) reactions for at least 2 hours post-vaccination, and then daily for the next 14 days. The vaccine mixture would be deemed safe if there were no statistically significant differences in the collective incidence of abnormal clinical observations and systemic or local adverse reactions across the three study sites.

**Table 1. Study design**

| Treatment Group     | Number of pigs (n) at each site | Total n | Treatment on Day 0  | Clinical Observations   |
|---------------------|---------------------------------|---------|---|---|
| 3FLEX Vaccine Group | Indiana site<br>n = 216         | 672     | 1.0 mL Ingelvac CircoFLEX® mixed with 1.0 mL Ingelvac MycoFLEX®, this mixture used to reconstitute Ingelvac PRRS MLV.<br>A single 2.0 mL dose of trivalent mixture given IM in the neck | For at least 2 hours post-vaccination (Day 0), then once daily from Day 1 to Day 14 |
|                     | Missouri site<br>n = 214        |         |   |   |
|                     | Nebraska site<br>n = 242        |         |   |   |
| Control Group       | Indiana site<br>n = 219         | 677     | 2.0 mL of water for injection, IM in the neck   |   |
|                     | Missouri site<br>n = 217        |         |   |   |
|                     | Nebraska site<br>n = 241        |         |   |   |

### Results

Abnormal clinical observations included scours, coughing, pneumonia, exudative epidermitis (greasy pig disease), lethargy, lameness, hernias, death and other conditions commonly observed in commercial pig production. The collective incidence of all clinical abnormalities across the three sites did not differ between treatment groups (vaccinates 7.1%, controls 6.4%; P=0.6517). None of the clinical abnormalities observed during the two week post-treatment period were attributed to the administration of the trivalent vaccine mixture. No systemic or local (injection site) reactions were observed.

### Conclusions

The 3FLEX™ vaccine mixture administered as a single 2.0 mL IM injection to pigs approximately three weeks of age was safe.