



Field safety data for Circumvent[®] PCV G2 and PCV-M G2¹

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Introduction

In order to gain USDA licensure, newly developed vaccines are evaluated for potency, efficacy and safety. Potency refers to the amount of antigen in the vaccine. Potency assays are developed to confirm that each batch or serial of vaccine produced in the future has sufficient antigen to be released for sale. Vaccine efficacy is demonstrated by vaccinating pigs and then challenging them with the pathogen under laboratory conditions. The final step for gaining a license is field safety studies where pigs are vaccinated in commercial swine herds and then closely monitored by practicing veterinarians for safety-related, adverse events following vaccination.

Over the past several years, the USDA has revised their guidance for field safety study protocols, resulting in more detailed safety evaluation of new vaccines. For example, study pigs are now individually identified by ear tag, and the frequency of post-vaccination observations has increased.

In general, a minimum of three studies conducted at three different swine operations in three different states are required. Within each study site, a minimum of 200 pigs is tested. For the Circumvent[®] G2 (referring to both Circumvent PCV G2 and Circumvent PCV-M G2) studies, two vaccination regimens (Option 1: 2 mL once at 3 weeks of age and Option 2: 1 mL at 3 days of age and 1 mL at 3 weeks of age) were evaluated, so each study site evaluated at least 400 pigs. This report contains the findings of the Circumvent G2 field safety studies conducted in three commercial swine operations.

Materials and Methods

Vaccine development: The same antigen and adjuvant used to make current Merck Animal Health PCV2 vaccines were used in formulating Circumvent G2. Alterations were made to facilitate the single-dose option and the lower-volume, two-dose option. In the safety study reported here, the vaccine was administered through a single 2-mL injection in pigs 3 weeks of age (Option 1) or as two 1-mL injections with the first injection at 3 days of age and the second injection 3 weeks later (Option 2).

Animals: The study was conducted at three geographically distinct sites in three different U.S. states. Approximately 235 pigs per site per dosing option were evaluated for a total of 1,422. Pigs were vaccinated per label with standard equipment and needles were changed between litters.

Evaluation: All pigs were individually observed for general health and for systemic and local injection site reactions between 1 to 4 hours following each vaccination, and daily for 14 days following each vaccination. If a pig had an adverse event, including any swelling at the injection site, present on the last scheduled day (Day 14) of observations, the pig was observed daily until resolution of the adverse event. During palpation of injection site area, events were recorded as none detected, <1.5 cm, 1.5 — 5.0 cm and >5.0 cm (no events >5.0 cm were observed). The data was tabulated and the results summarized.

Results

Systemic reactions: One pig out of 1,422 experienced an anaphylactic-type reaction where the pig fainted for approximately 30 seconds and then quickly recovered.

Local reactions:

- For the one-dose option (Option 1: 2 mL at 3 weeks of age), the size and duration of local reactions were minimal at all three study locations (see Charts 1 and 2).
- After the first injection at 3 days of age with the two-dose option (Option 2: 1 mL at 3 days of age and 1 mL at 3 weeks of age), the size and duration of local reactions were minimal at all three study locations (see Charts 3 and 4).
- After the second injection at 3 weeks of age with Option 2, the size and duration of local reactions were similar to current Circumvent products (see Charts 5 and 6).

Chart 1: Size of Option 1 local reactions

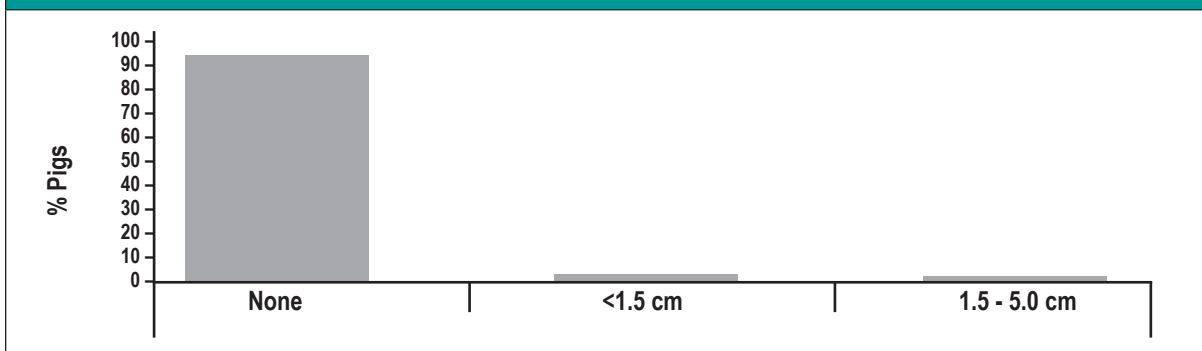


Chart 2: Duration of Option 1 local reactions

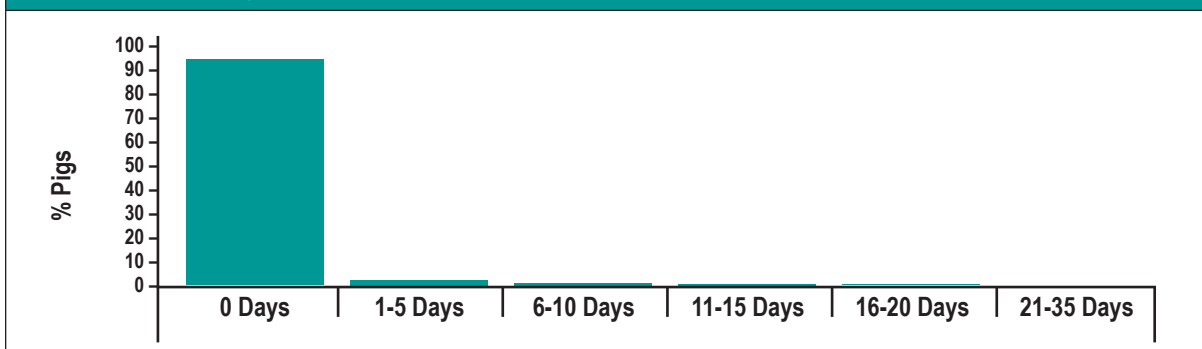


Chart 3: Size of Option 2 local reactions after first injection

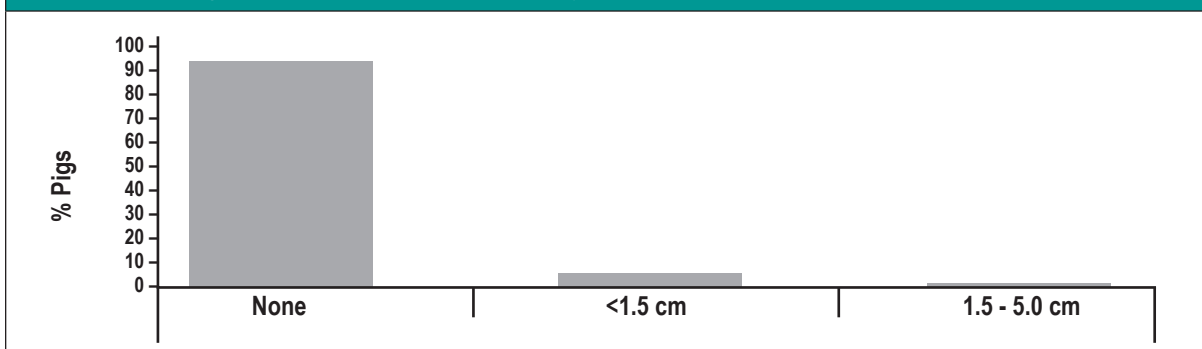


Chart 4: Duration of Option 2 local reactions after first injection

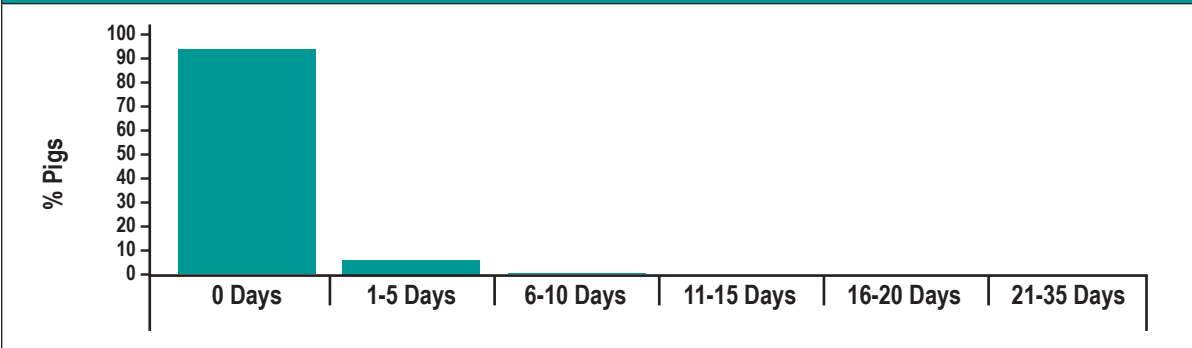


Chart 5: Size of Option 2 local reactions after second injection

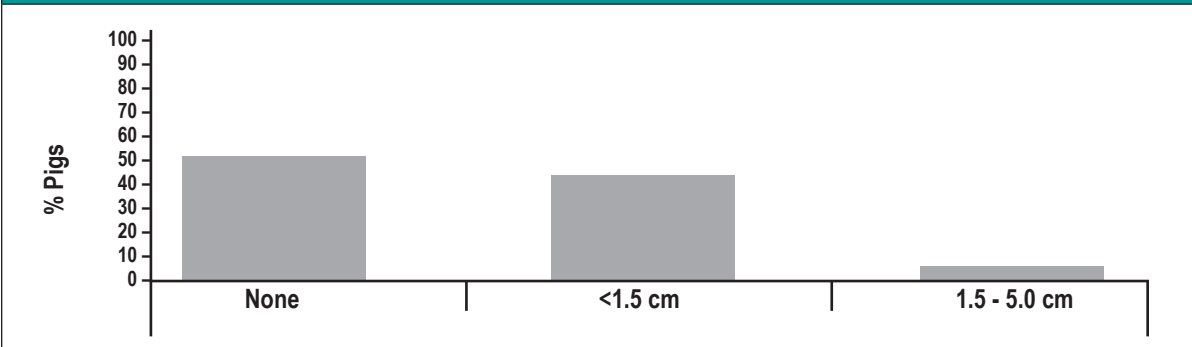
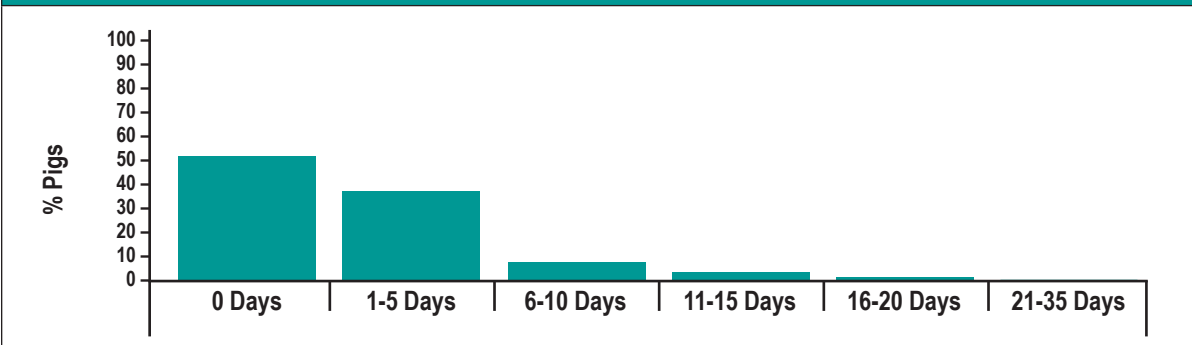


Chart 6: Duration of Option 2 local reactions after second injection



Discussion

With regard to systemic reactions, only one pig exhibited a brief adverse reaction immediately following vaccination. Any other systemic clinical signs observed during the studies were judged by the observing veterinarians to be unrelated to vaccination.

With regard to local reactions, the rate of swelling was low following the single 2-mL vaccination with Option 1 and the first 1-mL vaccination with Option 2. In addition, most of the reactions had subsided within 10 days for the single Option 1 vaccination and within 4 days for the first Option 2 vaccination.

With the second Option 2 vaccination (1 mL at 3 weeks of age), the rate of local reactions and duration were similar to what has been observed in previous field studies with the second dose of original Circumvent products. Accordingly, individual swine operations should expect a similar reaction rate with Circumvent G2 compared to their original product (Circumvent PCV or Circumvent PCV-M) after the second vaccination.

The three veterinarians who conducted the field safety studies all agreed that Circumvent G2 vaccines are safe to use.

To learn how to improve vaccination effectiveness and vaccine efficacy and safety, review the technical bulletin “The P’s of Safe and Effective Vaccination” found in the Technical Bulletins section at Circumvent-G2.com. This bulletin helps producers develop safe and effective vaccination procedures and protocols for their operations.

1. Data on file.

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