Example Individual Study Summaries

Efficacy Studies

Example 1: BVD PI calf study

Example 2: shedding/culture study for Leptospira

Example 3: lymphoid pathology study for porcine circovirus

Example 4: mortality/clinical signs for Haemophilus parasuis

Example 5: lung lesion scores for Mycoplasma hyopneumoniae

Example 6: placeholder for study data no longer on file

Example 7: temperatures and other signs for IBR respiratory study

Example 8: passive immunity/pig litters for E coli

Example 9: clinical signs for feline calicivirus

Example 13: 9CFR Marek's disease study

Example 17: placeholder for study submitted to USDA-APHIS prior to January 1, 2007

Example 18: placeholder for influenza strain swap, per VSM 800.111, that did not require vaccination-challenge

Example 19: placeholder for conditionally licensed platform product, per VSM 800.213, that did not require vaccination-challenge

Example 20: placeholder for prescription platform product, per VSM 800.214

Safety Studies

Example 10: field safety (typical study design)

Example 11: field safety (reproductive health, single offspring)

Example 12: field safety (reproductive health, litter offspring)

Example 14: field safety—poultry

Example 15: field safety—with events affirmed by licensee to have cause other than vaccination

Example 16: field safety—with explanatory note

Highlighted sections are OPTIONAL. All other data elements are required.

Updated: April 8, 2020

Example 1:

<table>
<tr><td>Study Type</td><td>Efficacy</td></tr>
<tr><td>Pertaining to</td><td>Bovine Virus Diarrhea Virus, Type 1 (BVDV1)</td></tr>
<tr><td>Study Purpose</td><td>Demonstrate effectiveness in pregnant animals against persistently infected calves</td></tr>
<tr><td>Product Administration</td><td>One dose administered subcutaneously one month prior to breeding.</td></tr>
<tr><td>Study Animals</td><td>20 vaccinated and 19 control Angus crossbred heifers, 16-18 months of age at first vaccination, seronegative (titer >2) to BVDV1 and BVDV2.</td></tr>
<tr><td>Challenge Description</td><td>BVDV1a Singer strain administered 230 days after vaccination (~169-194 days of gestation)</td></tr>
<tr><td>Observation interval after last treatment</td><td>Calves examined 50 days after challenge</td></tr>
<tr><td>Results</td><td>An animal was considered affected by the challenge if the calf had a BVDV serum neutralizing antibody titer ≥2 OR BVDV could be isolated from the calf.

19/19 controls and 6/20 vaccinates were affected.

<table>
<tr><th>Control ID</th><th>Virus</th><th>Antibody</th><th>Vacc ID</th><th>Virus</th><th>Antibody</th></tr>
<tr><td>1</td><td>+</td><td><2</td><td>1</td><td>-</td><td><2</td></tr>
<tr><td>2</td><td>+</td><td><2</td><td>2</td><td>-</td><td><2</td></tr>
<tr><td>3</td><td>+</td><td><2</td><td>3</td><td>+</td><td><2</td></tr>
<tr><td>4</td><td>+</td><td><2</td><td>4</td><td>-</td><td><2</td></tr>
<tr><td>5</td><td>+</td><td><2</td><td>5</td><td>-</td><td><2</td></tr>
<tr><td>6</td><td>+</td><td><2</td><td>6</td><td>-</td><td>8</td></tr>
<tr><td>7</td><td>+</td><td><2</td><td>7</td><td>-</td><td><2</td></tr>
<tr><td>8</td><td>+</td><td><2</td><td>8</td><td>+</td><td><2</td></tr>
<tr><td>9</td><td>+</td><td><2</td><td>9</td><td>-</td><td><2</td></tr>
<tr><td>10</td><td>+</td><td><2</td><td>10</td><td>-</td><td><2</td></tr>
<tr><td>11</td><td>+</td><td><2</td><td>11</td><td>-</td><td><2</td></tr>
<tr><td>12</td><td>+</td><td><2</td><td>12</td><td>-</td><td><2</td></tr>
<tr><td>13</td><td>+</td><td><2</td><td>13</td><td>+</td><td><2</td></tr>
<tr><td>14</td><td>+</td><td><2</td><td>14</td><td>+</td><td><2</td></tr>
<tr><td>15</td><td>+</td><td><2</td><td>15</td><td>-</td><td><2</td></tr>
<tr><td>16</td><td>+</td><td><2</td><td>16</td><td>-</td><td><2</td></tr>
<tr><td>17</td><td>+</td><td><2</td><td>17</td><td>-</td><td><2</td></tr>
<tr><td>18</td><td>+</td><td><2</td><td>18</td><td>-</td><td>32</td></tr>
<tr><td>19</td><td>+</td><td><2</td><td>19</td><td>-</td><td><2</td></tr>
<tr><td></td><td></td><td></td><td>20</td><td>-</td><td><2</td></tr>
</table>
</td></tr>
<tr><td>USDA Approval Date</td><td>mm/dd/yyyy</td></tr>
</table>

Example 2:

<table>
<tr><td>Study Type</td><td>Efficacy</td></tr>
<tr><td>Pertaining to</td><td>Leptospira pomona</td></tr>
<tr><td>Study Purpose</td><td>Pivotal efficacy against leptospirosis due to L. pomona</td></tr>
<tr><td>Product Administration</td><td>Two doses were administered subcutaneously (SC) or intramuscular (IM) at 21-day intervals.</td></tr>
<tr><td>Study Animals</td><td>3-month old calves were vaccinated twice (SC or IM) 21 days apart . Animals were seronegative to leptospiral serovars canicola, grippotyphosa, hardjo, icterohaemorrhagiae, and pomona. Twelve animals each were vaccinated by the SC and IM route; 12 animals served as controls.</td></tr>
<tr><td>Challenge Description</td><td>All animals were challenged with L. pomona 14 days after the last vaccination.</td></tr>
<tr><td>Observation interval after last treatment</td><td>Urine cultures were collected every two days for 10 days. Kidney and liver cultures were performed 14 days after challenge.</td></tr>
<tr><td>Results</td><td>Animals are considered affected by challenge if L. pomona could be recovered from any of the urine cultures or tissue cultures.

Urine Culture Results:
Controls: 8/12 (66.7%) positive
IM Vaccinates: 0/12 (0%)
SC Vaccinates: 0/12 (0%)

Urine Culture Data
<table>
<tr><th>Control ID</th><th>Day 2</th><th>Day 4</th><th>Day 6</th><th>Day 8</th><th>Day 10</th></tr>
<tr><td>1</td><td>-</td><td>-</td><td>-</td><td>-</td><td>-</td></tr>
<tr><td>2</td><td>-</td><td>+</td><td>+</td><td>+</td><td>+</td></tr>
<tr><td>3</td><td>-</td><td>+</td><td>+</td><td>-</td><td>-</td></tr>
<tr><td>4</td><td>-</td><td>+</td><td>-</td><td>+</td><td>-</td></tr>
<tr><td>5</td><td>+</td><td>+</td><td>+</td><td>+</td><td>+</td></tr>
<tr><td>6</td><td>+</td><td>+</td><td>+</td><td>+</td><td>-</td></tr>
<tr><td>7</td><td>-</td><td>-</td><td>-</td><td>-</td><td>-</td></tr>
<tr><td>8</td><td>-</td><td>-</td><td>-</td><td>-</td><td>-</td></tr>
<tr><td>9</td><td>-</td><td>+</td><td>+</td><td>-</td><td>-</td></tr>
<tr><td>10</td><td>-</td><td>+</td><td>+</td><td>+</td><td>+</td></tr>
<tr><td>11</td><td>+</td><td>+</td><td>-</td><td>-</td><td>-</td></tr>
<tr><td>12</td><td>-</td><td>+</td><td>+</td><td>-</td><td>+</td></tr>
<tr><td colspan="6">All vaccinates were negative at all sampling points</td></tr>
</table>
Three controls had positive kidney samples; none of the animals had positive liver samples.</td></tr>
<tr><td>USDA Approval Date</td><td>mm/dd/yyyy</td></tr>
</table>

Example 3:

<table>
<tr><td>Study Type</td><td>Efficacy</td></tr>
<tr><td>Pertaining to</td><td>Circovirus, Porcine, Type 2 (PCV2)</td></tr>
<tr><td>Study Purpose</td><td>Pivotal efficacy against porcine circovirus-associated disease</td></tr>
<tr><td>Product Administration</td><td>One dose administered intramuscularly</td></tr>
<tr><td>Study Animals</td><td>Caesarian-derived, colostrum deprived piglets randomly divided into 20 vaccinates and 20 controls. Piglets were 12 days of age at the time of vaccination.</td></tr>
<tr><td>Challenge Description</td><td>All pigs were challenged 31 days after vaccination with PCV2a.</td></tr>
<tr><td>Observation interval after last treatment</td><td>Lymphoid tissues examined 34 days after challenge</td></tr>
<tr><td>Results</td><td>Pigs were evaluated for the presence of PCV2 in lymphoid tissues, and pathologic changes in lymph nodes (lymphoid depletion). Tissues examined included tracheobronchial, mesenteric and sub-iliac lymph nodes, as well as the tonsil.

Results: PCV2 was recovered from lymphoid tissues of 3/20 vaccinates and 17/20 control piglets. Lymphoid depletion was observed in lymph nodes of 3/20 vaccinates and 16/20 controls.

<table>
<tr><th>Control ID</th><th>Virus</th><th>Lymphoid Depletion</th><th>Vacc ID</th><th>Virus</th><th>Lymphoid Depletion</th></tr>
<tr><td>1</td><td>+</td><td>+</td><td>1</td><td>-</td><td>-</td></tr>
<tr><td>2</td><td>+</td><td>+</td><td>2</td><td>-</td><td>-</td></tr>
<tr><td>3</td><td>-</td><td>-</td><td>3</td><td>+</td><td>+</td></tr>
<tr><td>4</td><td>+</td><td>+</td><td>4</td><td>-</td><td>-</td></tr>
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<tr><td>6</td><td>+</td><td>+</td><td>6</td><td>-</td><td>-</td></tr>
<tr><td>7</td><td>+</td><td>+</td><td>7</td><td>-</td><td>-</td></tr>
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<tr><td>11</td><td>+</td><td>+</td><td>11</td><td>-</td><td>-</td></tr>
<tr><td>12</td><td>-</td><td>-</td><td>12</td><td>-</td><td>-</td></tr>
<tr><td>13</td><td>+</td><td>+</td><td>13</td><td>+</td><td>+</td></tr>
<tr><td>14</td><td>+</td><td>+</td><td>14</td><td>-</td><td>-</td></tr>
<tr><td>15</td><td>+</td><td>+</td><td>15</td><td>-</td><td>-</td></tr>
<tr><td>16</td><td>+</td><td>+</td><td>16</td><td>-</td><td>-</td></tr>
<tr><td>17</td><td>+</td><td>+</td><td>17</td><td>-</td><td>-</td></tr>
<tr><td>18</td><td>+</td><td>+</td><td>18</td><td>-</td><td>-</td></tr>
<tr><td>19</td><td>+</td><td>+</td><td>19</td><td>-</td><td>-</td></tr>
<tr><td>20</td><td>+</td><td>-</td><td>20</td><td>-</td><td>-</td></tr>
</table>
</td></tr>
<tr><td>USDA Approval Date</td><td>mm/dd/yyyy</td></tr>
</table>

Example 4:

Study Type	Efficacy
Pertaining to	*Haemophilus parasuis*
Study Purpose	Efficacy against Glasser's disease
Product Administration	One dose administered intramuscularly
Study Animals	3-week old pigs randomly divided into 21 vaccinates and 20 controls.
Challenge Description	All pigs were challenged 21 days after vaccination with *H. parasuis*
Observation interval after last treatment	Observed daily for 21 days
Results	**Results:** Mortality after Challenge Vaccinates 5/18 Controls 13/20 Clinical Signs of Glasser's Disease after Challenge Vaccinate / Control Arthritis 4 of 18 / 5 of 20 Pneumonia 3 / 6 Pericarditis 0 / 2 Pleuritis 0 / 6

Control Animals

ID	Arthritis	Pneumonia	Pericarditis	Pleuritis	Death
1	Yes	No	No	No	Yes
2	No	Yes	No	Yes	Yes
3	No	No	No	No	No
4	Yes	Yes	Yes	Yes	Yes
5	No	No	No	No	No
6	No	No	No	No	No
7	No	No	No	No	Yes
8	No	Yes	Yes	Yes	Yes
9	Yes	No	No	No	No
10	No	No	No	No	Yes
11	No	No	No	No	Yes
12	No	Yes	Yes	Yes	Yes
13	No	No	No	No	Yes
14	Yes	No	No	No	No
15	No	Yes	No	Yes	Yes
16	No	No	No	No	No
17	No	No	No	No	No
18	Yes	Yes	Yes	Yes	Yes
19	No	No	No	No	Yes
20	No	No	No	No	Yes

Vaccinated Animals

ID	Arthritis	Pneumonia	Pericarditis	Pleuritis	Death
1	No	No	No	No	No
2	Yes	No	No	No	No
3	No	No	No	No	Yes
4	No	Yes	No	No	Yes
5	No	No	No	No	No
6	Yes	No	No	No	No
7	No	No	No	No	No
8	No	Yes	No	No	Yes
9	No	No	No	No	No
10	No	No	No	No	No
11	No	No	No	No	No
12	No	No	No	No	No
13	No	No	No	No	No
14	Yes	No	No	No	Yes
15	Yes	No	No	No	No
16	No	No	No	No	No
17	No	No	No	No	No
18	No	No	No	No	No
19	No	Yes	No	No	Yes

USDA Approval Date	mm/dd/yyyy

Example 5:

Study Type	Efficacy
Pertaining to	*Mycoplasma hyopneumoniae*
Study Purpose	Efficacy against respiratory disease
Product Administration (# doses, route of administration, interval between doses)	2 doses, given intramuscularly, 2 weeks apart
Study Animals (species, age at first product administration, number per treatment group)	Commercial pigs, 3 weeks of age. 32 vaccinates and 31 controls
Challenge Description (agent, route of administration, interval between last product dose and challenge)	*Mycoplasma hyopneumoniae*, given 3 weeks after final vaccination
Interval observed after challenge	Lungs evaluated 4 weeks after challenge
Results	The percent of the lung mass that was abnormal (consolidated) was calculated for every animal. 5-number summary for lung consolidation (%) ***Treatment*** ***Minimum*** ***Q_1*** ***Median*** ***Q_3*** ***Maximum*** *Controls* 4.4 7.5 13.2 18.0 26.3 *Vaccinates* 0.0 2.0 5.3 10.5 20.8 Raw data shown on attached page.
USDA Approval Date	mm/dd/yyyy

Lung consolidation scores (%), in order of rank:

Vaccinate	Control
0.1	0
0.1	0.3
0.1	1.0
0.1	2.3
0.1	2.5
0.2	3.0
0.3	3.1
0.3	4.5
0.3	6.7
0.5	8.2
0.5	8.2
0.6	10.8
0.7	11.0
1.1	11.3
1.3	12.1
1.8	12.5
1.9	14.1
2.0	14.8
5.3	15.1
5.7	18.0
10.2	20.1
10.7	23.2
10.9	24.8
33.3	35.0

Example 6:

Study Type	Efficacy
Pertaining to	Herpesvirus, Bovine (IBR)
Study Purpose	Efficacy against respiratory disease
Product Administration	
Study Animals	
Challenge Description	
Interval observed after challenge	
Results	Study data were evaluated by USDA-APHIS prior to product licensure and met regulatory standards for acceptance at the time of submission. Study data, however, are no longer available.
USDA Approval Date	May 21, 1962

Example 7:

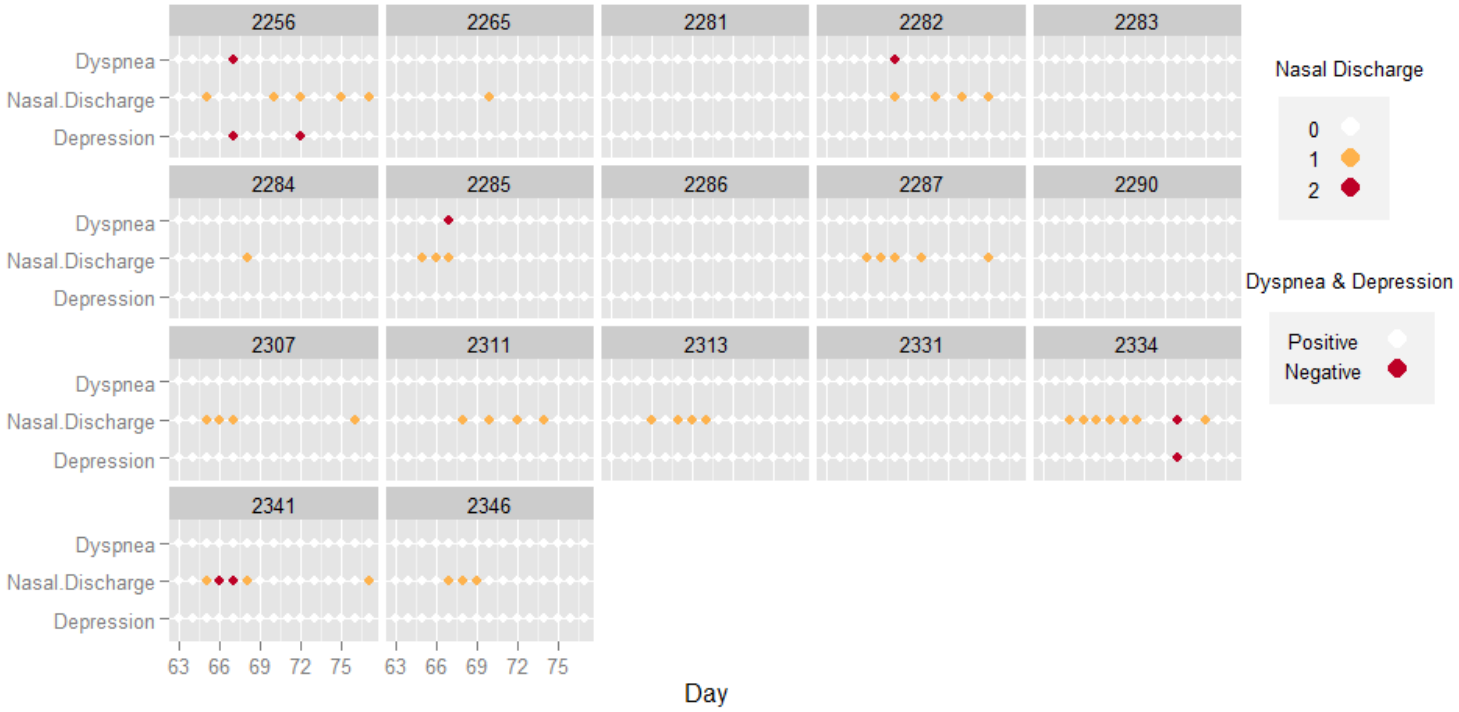
Study Type	Efficacy
Pertaining to	Herpesvirus, bovine (IBR)
Study Purpose	Demonstrate effectiveness against infectious bovine rhinotracheitis
Product Administration	Single dose, administered subcutaneously
Study Animals	Forty calves, seronegative to IBR, 3 months of age, 20 vaccinates and 20 controls
Challenge Description	IBR virus administered 14 days after vaccination
Interval observed after challenge	Calves observed daily for 14 days after challenge
Results	Animals were considered affected by the challenge if they had a temperature ≥104.0 on more than one day AND demonstrated at least one clinical sign (depression, dyspnea, or purulent nasal discharge) on at least one day. Totals: 16/18 controls affected 0/17 vaccinates affected Raw data: See attached.
USDA Approval Date	mm/dd/yyyy

		Rectal	Temperatures														
Controls																	
Calf	**Day 62**	**63**	**64**	**65**	**66**	**67**	**68**	**69**	**70**	**71**	**72**	**73**	**74**	**75**	**76**	**77**	**Classification**
2245	101.9	101.2	101.2	102.2	104.8	104.5	104.7	102.5	103.1	104.1	101.2	100.7	100.5	102	101.3	101	Positive
2267	101.2	101.6	101.7	104.6	104.9	103.1	104	103.2	101.6	101	101.6	100.3	100.9	100.6	101	100.4	Positive
2273	101.9	101.5	101.9	103.6	105	104.9	104.9	103	101.6	101.8	100.7	101.7	101.1	101.1	101	100.9	Positive
2274	101.3	101.9	101.2	103.1	103.5	106.2	105.4	104.2	101	103.9	101.2	101.8	101.2	101.1	101	102.6	Positive
2291	101.8	101	101.4	103.3	104.2	104.6	104	103	102.3	101.7	100.6	101.5	100.8	101.1	101.2	100.4	Positive
2298	101.2	102.7	102	102.3	103.4	104	104	102.4	103.5	102.7	101.9	101	101.2	101.6	101.4	101.8	Positive
2302	101.4	101.4	101.6	101.6	102	103.8	103.7	103.3	102	101.5	101.5	101.2	100.7	101.6	101.6	101.7	Negative
2310	101.6	102	101.7	104	103.3	105.4	104.8	103.7	103.3	104.1	103.5	101.5	100.7	101.7	101.2	101.4	Positive
2318	101.8	101.8	101.6	104.8	106.1	106	105.9	105	102.6	103.2	103.3	101.6	100.6	100.7	101.6	101.5	Positive
2320	102.3	101.2	102.2	104.1	103.4	104.1	103.5	103.7	103	103.1	103.3	101.9	101.7	102.8	103.4	104.2	Positive
2323	100.5	101.2	100.6	103.3	104.4	104.9	104.7	103.9	103.6	102.1	101.7	100.7	100.5	101	101.6	102.3	Positive
2326	101.3	101.9	101	103.2	103.3	103.7	104	101.6	101.4	102.2	101.4	101.6	101	101.1	101.3	101.4	Negative
2329	102.4	103.4	101.2	103.9	104.5	104.1	103.5	103.2	103.2	103.2	100.6	102.2	100.1	100.7	100.9	102.1	Positive
2344	102.1	102	100.6	104.1	103.4	104.2	103.5	104	102.1	101.3	100.6	101	100.6	100.5	101.5	101.4	Positive
2345	101	102.1	101.1	102.9	104	104.4	104.3	102.1	101.1	101	100.6	101.3	101.1	101.1	101	101	Positive
2348	101.5	102.5	101.4	104.6	104	102.9	102.7	102.6	103	102	102.3	101.3	101.5	101.4	101.3	102.1	Positive
2350	101.2	101.6	103	103.8	103.9	104.2	104.2	103.8	103	102.9	102.7	101.3	101.7	101.1	101.3	101.8	Positive
2352	101.5	101.4	101.2	102.5	104.2	103.5	104.5	102.8	102.7	101.4	101.1	100.6	101.1	100.6	101.7	101.4	Positive
Vaccinates																	
2256	100.9	102.3	102.2	103.2	102.6	103.9	103.9	102.9	101.7	102.3	102.7	101.2	102.1	101.6	101.7	101.9	Negative
2265	101	101.8	101.4	101.8	101.4	102.4	104.1	103.8	101.3	101.4	101.6	101.8	101.2	101.6	101.7	101.8	Negative
2281	101.1	101.4	100.9	100.9	102.8	101.3	101.1	101	100.7	101.5	101.1	101	101.3	100.5	101.5	101.7	Negative
2282	100.7	101.7	101	101.7	102.7	102.2	103.9	104.6	103.9	101.3	100.8	101.1	100.8	101.1	100.8	100.3	Negative
2283	101.1	101.1	101.4	102.4	102.8	102.3	102.3	103.9	103.8	101.6	101.3	101.6	101.1	101.3	101.6	101.8	Negative
2284	101.4	101.3	101.5	101.4	102.6	102.5	102	101.6	101.8	101.3	101.6	101.6	101.3	101.5	101.5	101.1	Negative
2285	101.5	101.6	101.5	101.4	103.5	103.4	103.8	103.7	101.2	101.5	101.9	102.4	101.9	101.8	101.4	102	Negative
2286	101.8	101.4	101	103.6	104	103.9	103.8	101.6	101.9	102.4	102	101.7	101.4	101.7	101.6	102.1	Negative
2287	101.3	101.8	101.3	103.1	104.4	103.8	103	101.5	101.3	101.6	101.7	101.2	101.6	101.6	102.2	101.7	Negative
2290	101.1	101.6	102	102.3	102.4	101.4	101.7	101.1	101.9	101.9	101.4	101.9	101.2	101.5	102.1	100.9	Negative
2307	101.1	101.5	101.7	101.4	102.4	101.6	101.5	101	101.4	101.2	100.3	102.1	101.5	102.1	102	101.4	Negative
2311	101.3	101.5	101.3	102.6	103.6	103.9	104.1	103.8	101.5	101.5	101.7	101	100.8	101.1	101.6	101.8	Negative
2313	101	101.2	101.3	101.9	103.1	101.6	101.6	101.5	101.5	102.2	101	101.2	101.1	100.8	101.6	101.3	Negative
2331	101.5	102	101.9	101.8	102.1	103.1	103.7	103.9	103.9	102.6	101.8	101.4	101.7	101.8	101.4	101.7	Negative
2334	100.9	102.3	102.3	103.4	101.9	101.8	101.6	101.4	101.7	101.8	100.8	101	102.3	102	101.7	101.5	Negative
2341	102.1	101.7	101.7	101.9	101.7	103.7	104.5	103.8	103.7	102.2	102.4	102.2	102.2	101.2	101.5	102.5	Negative
2346	102.3	101.5	102	102.8	104	103.5	103.1	100.7	101.2	102	101.1	101.9	102.4	104.1	101	102.7	Positive

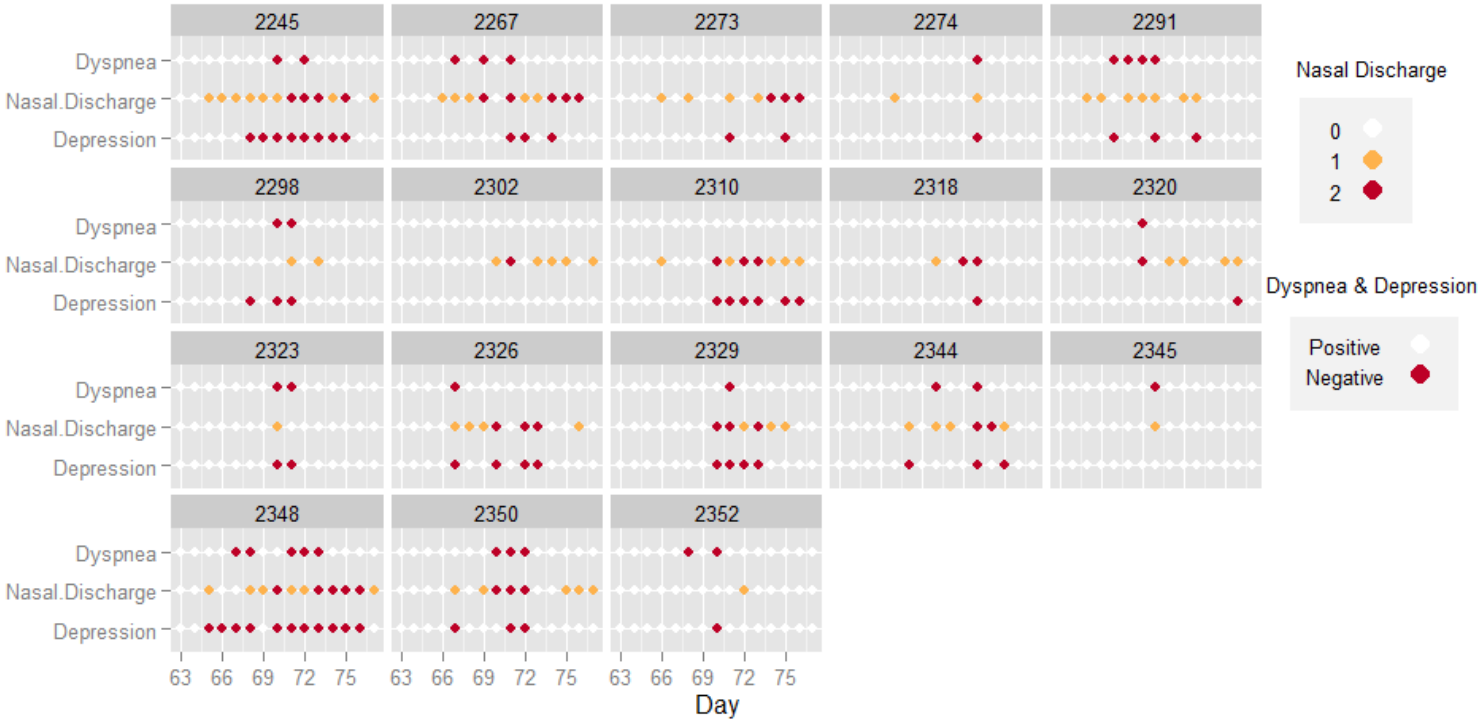
Key to nasal discharge score:
0=normal
1=serous discharge
2=purulent discharge

Clinical Sign Data:

Vaccinates



Controls



Example 8:

<table>
<tr><td>Study Type</td><td>Efficacy</td></tr>
<tr><td>Pertaining to</td><td>Escherichia coli</td></tr>
<tr><td>Study Purpose</td><td>Efficacy against neonatal diarrhea due to K99 pilus-expressing E coli</td></tr>
<tr><td>Product Administration</td><td>2 doses, administered intramuscularly to pregnant gilts, approximately 5 and 2 weeks prior to farrowing</td></tr>
<tr><td>Study Animals</td><td>Crossbred commercial gilts, 6 months of age at breeding. 20 vaccinated gilts and 10 control gilts. Healthy piglets in each litter were challenged.</td></tr>
<tr><td>Challenge Description</td><td>K99+ E coli given to neonatal piglets 2 hours after first nursing (colostrum)</td></tr>
<tr><td>Interval observed after challenge</td><td>Observed daily for 7 days after challenge</td></tr>
<tr><td>Results</td><td>Mortality in each litter was assessed.

Total pigs dead:
From vaccinated sows: 21/150 (14%)
From control sows: 48/67 (72%)

Figures below represent piglets dying/total piglets challenged in each litter.
<table>
<tr><td>Vaccinates</td><td>Controls</td></tr>
<tr><td>0/8</td><td>1/6</td></tr>
<tr><td>0/7</td><td>3/8</td></tr>
<tr><td>0/9</td><td>4/7</td></tr>
<tr><td>0/5</td><td>5/7</td></tr>
<tr><td>0/8</td><td>5/7</td></tr>
<tr><td>0/6</td><td>5/6</td></tr>
<tr><td>0/9</td><td>7/8</td></tr>
<tr><td>0/8</td><td>4/4</td></tr>
<tr><td>0/7</td><td>6/6</td></tr>
<tr><td>0/7</td><td>8/8</td></tr>
<tr><td>1/6</td><td></td></tr>
<tr><td>1/9</td><td></td></tr>
<tr><td>1/7</td><td></td></tr>
<tr><td>1/8</td><td></td></tr>
<tr><td>2/7</td><td></td></tr>
<tr><td>2/9</td><td></td></tr>
<tr><td>2/6</td><td></td></tr>
<tr><td>3/9</td><td></td></tr>
<tr><td>3/7</td><td></td></tr>
<tr><td>5/8</td><td></td></tr>
</table></td></tr>
<tr><td>USDA Approval Date</td><td>mm/dd/yyyy</td></tr>
</table>

Example 9:

<table>
<tr><td>Study Type</td><td>Efficacy</td></tr>
<tr><td>Pertaining to</td><td>Feline calicivirus</td></tr>
<tr><td>Study Purpose</td><td>Demonstrate efficacy against feline calicivirus</td></tr>
<tr><td>Product Administration</td><td>Two doses, administered subcutaneously, 3 weeks apart.</td></tr>
<tr><td>Study Animals</td><td>20 vaccinates and 10 controls, 9-11 weeks of age.</td></tr>
<tr><td>Challenge Description</td><td>Feline calicivirus was administered 3 weeks after the last vaccination.</td></tr>
<tr><td>Interval observed after challenge</td><td>All cats were observed daily for clinical symptoms for 2 weeks after challenge.</td></tr>
<tr><td>Results</td><td>Animals displaying clinical signs were considered to be affected by the challenge.

Number affected:
Vaccinates: 2/20
Controls: 10/10

Raw data:

A disease severity code was created.

<table>
<tr><th>Clinical Observations</th><th>Code</th></tr>
<tr><td>Normal</td><td>A</td></tr>
<tr><td>Single shallow mouth ulcer</td><td>B</td></tr>
<tr><td>Multiple distinct shallow ulcers, or an ulcer with deeper erosion</td><td>C</td></tr>
<tr><td>Mouth ulcers with excessive erosion</td><td>D</td></tr>
<tr><td>Mouth ulcers with bleeding and/or salivation</td><td>E</td></tr>
<tr><td>Mouth and/or nasal erosions with anorexia and depression</td><td>F</td></tr>
<tr><td>Labored breathing and/or pneumonia</td><td>G</td></tr>
</table>

Data table is appended to end of this summary.</td></tr>
<tr><td>USDA Approval Date</td><td>mm/dd/yyyy</td></tr>
</table>

	Clinical Code By Post-Challenge Day													
	Day 0	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7	Day 8	Day 9	Day 10	Day 11	Day 12	Day 13
Vacc 1	A	A	A	A	A	A	A	A	A	A	A	A	A	A
Vacc 2	A	A	A	A	A	A	A	A	A	A	A	A	A	A
Vacc 3	A	A	A	A	A	B	B	B	C	C	B	A	A	A
Vacc 4	A	A	A	A	A	A	A	A	A	A	A	A	A	A
Vacc 5	A	A	A	A	A	A	A	A	A	A	A	A	A	A
Vacc 6	A	A	A	A	A	A	A	A	A	A	A	A	A	A
Vacc 7	A	A	A	A	A	A	A	A	A	A	A	A	A	A
Vacc 8	A	A	A	A	A	A	A	A	A	A	A	A	A	A
Vacc 9	A	A	A	A	C	C	C	C	C	C	C	C	B	B
Vacc 10	A	A	A	A	A	A	A	A	A	A	A	A	A	A
Vacc 11	A	A	A	A	A	A	A	A	A	A	A	A	A	A
Vacc 12	A	A	A	A	A	A	A	A	A	A	A	A	A	A
Vacc 13	A	A	A	A	A	A	A	A	A	A	A	A	A	A
Vacc 14	A	A	A	A	A	A	A	A	A	A	A	A	A	A
Vacc 15	A	A	A	A	A	A	A	A	A	A	A	A	A	A
Vacc 16	A	A	A	A	A	A	A	A	A	A	A	A	A	A
Vacc 17	A	A	A	A	A	A	A	A	A	A	A	A	A	A
Vacc 18	A	A	A	A	A	A	A	A	A	A	A	A	A	A
Vacc 19	A	A	A	A	A	A	A	A	A	A	A	A	A	A
Vacc 20	A	A	A	A	A	A	A	A	A	A	A	A	A	A
Control 1	A	A	D	F	F	G	G	F	E	D	D	D	C	C
Control 2	A	A	A	B	C	C	C	C	C	C	C	B	B	B
Control 3	A	A	A	C	C	D	C	C	C	B	B	B	A	A
Control 4	A	A	A	B	B	C	C	C	C	C	C	C	C	A
Control 5	A	A	A	C	F	F	E	E	E	E	E	D	C	D
Control 6	A	A	A	B	B	B	B	B	B	B	B	B	A	A
Control 7	A	A	A	A	B	D	D	D	D	D	D	D	C	B
Control 8	A	A	A	A	F	D	D	D	D	D	C	B	A	A
Control 9	A	A	A	A	A	A	A	A	A	A	A	C	B	A
Control 10	A	A	A	C	C	C	C	C	C	C	B	B	B	B

Example 10:

<table>
<tr><td>Study Type</td><td>Safety</td></tr>
<tr><td>Pertaining to</td><td>ALL</td></tr>
<tr><td>Study Purpose</td><td>Demonstrate safety of product under typical use conditions.</td></tr>
<tr><td>Product Administration</td><td>2 Doses administered at 2 week intervals by either IM or SQ route.</td></tr>
<tr><td>Study Animals</td><td>300 pigs ranging in age from 3 weeks to 12 weeks at each of 3 sites. 1/3 were vaccinated intramuscularly (IM), 1/3 subcutaneously (SQ), and 1/3 kept as controls. 1/3 of each treatment group were of minimum age recommended for product administration.</td></tr>
<tr><td>Challenge Description</td><td>NA</td></tr>
<tr><td>Observation interval after last treatment</td><td>Animals were observed every hour for 4 hrs after each injection and then twice daily through 14 days after the last vaccination.</td></tr>
<tr><td>Results</td><td>
<table>
<tr><th>Frequency of adverse events
(150 total pigs per group)</th><th>IM min age</th><th>IM others</th><th>SQ min age</th><th>SQ others</th><th>Control min age</th><th>Control others</th></tr>
<tr><td>Injection Site Swelling
(transient, ≤2 cm diameter)</td><td>0</td><td>0</td><td>21</td><td>33</td><td>0</td><td>0</td></tr>
<tr><td>Respiratory Distress</td><td>0</td><td>0</td><td>0</td><td>1</td><td>0</td><td>0</td></tr>
<tr><td>Pain on injection</td><td>3</td><td>0</td><td>8</td><td>3</td><td>3</td><td>0</td></tr>
<tr><td>No adverse events</td><td>147</td><td>150</td><td>123</td><td>111</td><td>147</td><td>150</td></tr>
</table>
</td></tr>
<tr><td>USDA Approval Date</td><td>mm/dd/yyyy</td></tr>
</table>

Example 11:

<table>
<tr><td>Study Type</td><td>Safety</td></tr>
<tr><td>Pertaining to</td><td>ALL</td></tr>
<tr><td>Study Purpose</td><td>Safety in pregnant mares</td></tr>
<tr><td>Product Administration</td><td>Two doses, administered intramuscularly, at a 3-week interval</td></tr>
<tr><td>Study Animals</td><td>Pregnant mares, >2 years of age: separate groups vaccinated at each trimester of gestation. Similar sized groups in each trimester were maintained as controls.</td></tr>
<tr><td>Challenge Description</td><td>NA</td></tr>
<tr><td>Interval observed after challenge</td><td>Observed through birth of foals</td></tr>
<tr><td>Results</td><td>
<table>
<tr><td>Treatment</td><td>Vaccinated</td><td>Confirmed pregnant</td><td>Healthy foals</td></tr>
<tr><td>1st trimester/product</td><td>200</td><td>178</td><td>169</td></tr>
<tr><td>1st trimester/control</td><td>196</td><td>181</td><td>170</td></tr>
<tr><td>2nd trimester/product</td><td>198</td><td>*</td><td>195</td></tr>
<tr><td>2nd trimester/control</td><td>190</td><td>*</td><td>185</td></tr>
<tr><td>3rd trimester/product</td><td>201</td><td>*</td><td>200</td></tr>
<tr><td>3rd trimester/control</td><td>196</td><td>*</td><td>196</td></tr>
</table>
*Pregnancy confirmed prior to enrollment in study.
</td></tr>
<tr><td>USDA Approval Date</td><td>mm/dd/yyyy</td></tr>
</table>

Example 12:

Study Type	Safety
Pertaining to	ALL
Study Purpose	Demonstrate safety in pregnant gilts
Product Administration	1 dose, 5 weeks prior to farrowing
Study Animals	Pregnant crossbred gilts: 75 vaccinated and 75 controls
Challenge Description	NA
Interval observed after challenge	Observed from vaccination through farrowing. Litter size and health were documented.
Results	No adverse events noted in gilts. See appended page for results of litter evaluation.
USDA Approval Date	mm/dd/yyyy

Control group:

Animal	Live Births	Dead	Mummified	Animal	Live Births	Dead	Mummified
1	10	4	0	38	10	1	1
2	10	0	1	39	11	2	0
3	11	0	0	40	10	8	0
4	9	2	1	41	11	1	2
5	11	1	0	42	11	2	2
6	13	1	0	43	17	0	0
7	17	0	1	44	10	0	0
8	8	0	0	45	13	0	0
9	12	0	0	46	15	1	0
10	1	0	1	47	9	2	0
11	13	3	0	48	13	0	0
12	3	1	1	49	11	3	0
13	11	0	0	50	14	0	0
14	12	1	0	51	13	2	0
15	12	0	0	52	12	0	0
16	16	1	1	53	7	1	0
17	12	1	0	54	9	1	2
18	10	0	0	55	11	1	1
19	13	0	0	56	13	1	1
20	13	1	0	57	13	1	0
21	14	3	0	58	13	1	0
22	14	2	0	59	10	0	1
23	8	0	0	60	8	3	0
24	6	0	0	61	10	0	0
25	7	1	0	62	4	0	0
26	6	1	0	63	5	0	0
27	9	2	0	64	13	3	0
28	8	0	0	65	8	1	0
29	13	0	0	66	4	0	0
30	5	4	0	67	13	0	0
31	15	1	0	68	13	0	1
32	10	1	0	69	13	0	0
33	13	3	1	70	12	0	0
34	11	4	1	71	7	4	0
35	10	3	2	72	17	0	0
36	16	0	0	**Total**	**775**	**83**	**24**
37	10	3	3	**Percentage**	**87.90%**	**9.40%**	**2.70%**

Vaccinate group:

Animal	Live Births	Dead	Mummified	Animal	Live Births	Dead	Mummified
1	9	0	2	38	9	4	0
2	12	2	0	39	11	1	0
3	14	1	1	40	14	1	0
4	14	1	0	41	6	6	1
5	8	2	0	42	15	0	0
6	11	1	1	43	13	0	0
7	10	1	0	44	11	0	1
8	12	0	0	45	14	0	0
9	9	3	2	46	8	1	0
10	17	3	1	47	13	2	2
11	14	0	0	48	11	1	1
12	11	3	1	49	9	1	1
13	8	2	0	50	8	5	0
14	14	2	0	51	10	1	1
15	8	5	0	52	13	2	0
16	14	1	0	53	13	4	0
17	9	0	0	54	11	0	0
18	10	1	2	55	12	0	0
19	0	0	21	56	11	2	0
20	4	1	0	57	8	4	0
21	12	0	0	58	9	7	1
22	11	2	0	59	10	1	0
23	9	1	1	60	14	3	1
24	10	2	1	61	10	3	0
25	14	0	0	62	12	2	0
26	8	0	1	63	9	0	0
27	9	0	2	64	12	1	0
28	7	0	0	65	9	1	0
29	14	2	0	66	8	2	0
30	7	1	0	67	7	0	0
31	13	2	0	68	11	1	1
32	15	1	0	69	10	0	0
33	14	1	0	70	7	2	0
34	13	3	1	71	6	0	0
35	9	3	0	72	10	2	0
36	9	3	0	73	11	1	0
37	15	0	0	74	14	0	4

Vaccinate group, continued:

Animal	Live Births	Dead	Mummified	Animal	Live Births	Dead	Mummified
75	8	0	0	114	8	0	0
76	10	0	0	115	13	0	0
77	12	0	0	116	15	1	0
78	6	0	1	117	13	1	0
79	10	1	0	118	16	0	0
80	9	3	0	119	10	0	0
81	4	2	0	120	9	5	0
82	14	2	2	121	9	0	0
83	11	0	0	122	7	1	2
84	10	0	0	123	8	1	0
85	11	0	2	124	8	2	0
86	5	0	0	125	11	1	0
87	10	0	0	126	5	0	0
88	12	1	0	127	12	2	0
89	5	8	2	128	10	1	0
90	10	4	0	129	10	2	0
91	12	1	0	130	13	0	0
92	10	2	1	131	10	0	0
93	12	0	0	132	11	0	0
94	13	1	0	133	10	0	0
95	10	1	1	134	12	0	0
96	10	1	0	135	11	0	1
97	10	2	0	136	7	0	0
98	10	1	0	137	11	0	0
99	10	0	0	138	6	5	0
100	9	3	0	139	12	1	1
101	15	1	2	140	14	1	0
102	10	0	0	141	9	2	0
103	15	1	0	142	13	1	1
104	10	1	0	143	8	3	0
105	15	1	0	144	7	0	0
106	9	1	0	145	12	2	0
107	10	0	0	146	1	1	0
108	8	1	0	147	15	0	0
109	10	1	0	148	12	0	2
110	3	0	0	149	14	1	0
111	8	1	0	**Total**	**1149**	**125**	**55**
112	4	0	0	**Percentage**	**85.78%**	**10.37%**	**3.85%**
113	10	0	0				

Example 13:

Study Type	Efficacy
Pertaining to	Marek's Disease Virus serotype 1
Study Purpose	Demonstrate efficacy against very virulent Marek's disease
Product Administration	One dose administered subcutaneously at 1 day of age
Study Animals	Day-old chicks divided into 4 groups Group 1 vaccinated with test product and challenged Group 2 sham vaccinated and challenged (control) Group 3 sham vaccinated non-challenged (control) Group 4 vaccinated with a serotype 3 Marek's vaccine and challenged (control)
Challenge Description	Serotype-1 (SR-1) RB1B strain administered at 4 days post vaccination
Interval observed after challenge	Observed daily for 7 weeks and then evaluated for internal lesions
Results	Vaccinates and controls were evaluated in terms of Marek's disease clinical signs and/or grossly observable lesions per the criteria in 9 CFR 113.330(c)(4) & (5). Birds with clinical signs and/or observable lesions: Group 1: 5/34 Group 2: 31/34 Group 3: 0/35 Group 4: 8/33 Requirements of 9 CFR 113.330(c)(4) & (5) were met. Raw data on attached page
USDA Approval Date	January 1, 2008

Raw data shown below for birds classified as positive. All other birds normal.

			Tumors In									
Group/Bird	**Emaciation**	**Locomotor/ Paralysis**	**Kidney**	**Spleen**	**Gonads**	**Breast**	**Liver**	**Intestine**	**Heart**	**Ascites**	**Yolk Sac Infection**	**Reason Not Given**
Group 1/1											x	
Group 1/2		x										
Group 1/3	x											
Group 1/4	x			x								
Group 1/5			x									
Group 2/1	x											
Group 2/2		x			x							
Group 2/3		x			x							
Group 2/4	x		x	x								
Group 2/5			x	x		x						
Group 2/6	x		x		x							
Group 2/7	x											
Group 2/8	x		x									
Group 2/9	x		x									
Group 2/10	x											
Group 2/11	x		x									
Group 2/12	x				x							
Group 2/13	x		x									
Group 2/14	x		x		x		x					
Group 2/15	x											
Group 2/16	x											
Group 2/17		x										
Group 2/18		x			x							
Group 2/19	x				x							
Group 2/20	x		x									
Group 2/21	x											
Group 2/22					x							
Group 2/23			x				x					
Group 2/24	x		x									
Group 2/25	x		x									
Group 2/26												x
Group 2/27												x
Group 2/28												x
Group 2/29												x
Group 2/30												x

			Tumors In									
Group/Bird	**Emaciation**	**Locomotor/ Paralysis**	**Kidney**	**Spleen**	**Gonads**	**Breast**	**Liver**	**Intestine**	**Heart**	**Ascites**	**Yolk Sac Infection**	**Reason Not Given**
Group 2/31												**x**
Group 4/1	**x**											
Group 4/2	**x**		**x**									
Group 4/3								**x**		**x**		
Group 4/4			**x**		**x**	**x**						
Group 4/5	**x**		**x**				**x**		**x**			
Group 4/6		**x**										
Group 4/7												**x**
Group 4/8												**x**

Example 14:

Study Type	Safety
Pertaining to	All fractions
Study Purpose	Field safety
Product Administration	Single dose by either the *in ovo* or subcutaneous (SQ) route.
Study Animals	Commercial layer or broilers, at 18 day-old embryos (*in ovo*) or day-old chicks (SQ). 3 independent study sites.
Challenge Description	Not applicable
Interval observed after challenge	Layer pullets were observed for 8 weeks, Broiler chicks were observed until slaughter.
Results	**--For illustrative purposes, below are examples of acceptable formatting, depending on details of study design. They do not necessarily correspond to the design details listed above--**

Location	Treatment	Total Placed	21 Day Mortality	% Mortality	% Hatchability	% Condemnation
1	SQ	16,400	200	1.4	N/A	0.1
1	*In ovo*	16,400	205	1.6	86.9	0.05
1	Control	16,400	206	1.4	87.4	0.07
2	SQ	20,000	300	1.3	N/A	0.09
2	*In ovo*	20,000	303	2	87.8	0.12
2	Control	20,000	312	2	85.6	0.1
3	SQ	21,000	495	2.5	N/A	0.09
3	*In ovo*	21,000	480	2.2	90.2	0.04
3	Control	21,000	475	1.4	86.7	0.1

N/A is not applicable

Location	Treatment	Total Placed	% Mortality	% Hatchability	% Condemnation
1	SQ	16,400	1.4	N/A	0.1
1	*In ovo*	16,400	1.6	86.9	0.05
1	Control	16,400	1.4	87.4	0.07
2	SQ	20,000	1.3	N/A	0.09
2	*In ovo*	20,000	2	87.8	0.12
2	Control	20,000	2	85.6	0.1
3	SQ	21,000	2.5	N/A	0.09
3	*In ovo*	21,000	2.2	90.2	0.04
3	Control	21,000	1.4	86.7	0.1

N/A is not applicable

In ovo Route

Site	Number of chickens	Mortality (%)		Condemnation (%)		Hatchability (%)	
		Vaccinates	Controls	Vaccinates	Controls	Vaccinates	Controls
1	43,119	4.78	3.23	0.27	0.07	88	85
2	44,600	4.14	4.66	0.20	0.37	89	88
3	43,400	5.40	5.02	0.34	0.27	90	95
4	90,437	1.17	1.78	0.09	0.13	91	93

SQ Route

Site	Number of chickens	Mortality (%)		Condemnation (%)	
		Vaccinates	Controls	Vaccinates	Controls
1	43,119	4.78	3.23	0.27	0.07
2	44,600	4.14	4.66	0.20	0.37
3	43,400	5.40	5.02	0.34	0.27
4	90,437	1.17	1.78	0.09	0.13

No adverse reactions attributable to the vaccine were recorded.

USDA Approval Date	MMDDYYYY

Example 15.

<table>
<tr><td>Study Type</td><td>Safety</td></tr>
<tr><td>Pertaining to</td><td>ALL</td></tr>
<tr><td>Study Purpose</td><td>Demonstrate safety of product under typical use conditions</td></tr>
<tr><td>Product Administration</td><td>Two doses administered intramuscularly at a 3 week interval by IM route</td></tr>
<tr><td>Study Animals</td><td>675 cats total at 4 sites. Minimum age 8 weeks.</td></tr>
<tr><td>Challenge Description</td><td>NA</td></tr>
<tr><td>Interval observed after challenge</td><td>Animals were observed for 1 hour after each injection and then daily for 21 days.</td></tr>
<tr><td>Results</td><td>
<table>
<tr><th rowspan="2">Group at site</th><th rowspan="2">Total number animals</th><th colspan="3">Maximum size of injection site reaction</th><th rowspan="2">Injection site reactions not observed</th></tr>
<tr><th>< 0.5 cm</th><th>0.5-1.5 cm</th><th>> 1.5 cm</th></tr>
<tr><td>1</td><td>200</td><td>5</td><td>7</td><td>0</td><td>188</td></tr>
<tr><td>2</td><td>200</td><td>2</td><td>8</td><td>0</td><td>190</td></tr>
<tr><td>3</td><td>200</td><td>10</td><td>6</td><td>0</td><td>184</td></tr>
<tr><td>4</td><td>75</td><td>10</td><td>9</td><td>2</td><td>53</td></tr>
</table>
Injection site swellings were observed after the second vaccination and all resolved by 2 days post vaccination.
<table>
<tr><th>VeDDRA Code</th><th>Total number of animals</th><th>Percent of all animals</th></tr>
<tr><td>Normal</td><td>494</td><td>73.29%</td></tr>
<tr><td>Aggression</td><td>2</td><td>0.30%</td></tr>
<tr><td>Injection site self trauma</td><td>3</td><td>0.45%</td></tr>
<tr><td>Vocalization</td><td>3</td><td>0.45%</td></tr>
<tr><td>Lymphadenopathy</td><td>2</td><td>0.30%</td></tr>
<tr><td>General Pain</td><td>2</td><td>0.30%</td></tr>
<tr><td>Weakness</td><td>1</td><td>0.15%</td></tr>
<tr><td>Injection site swelling (cellulitis)</td><td>1</td><td>0.15%</td></tr>
<tr><td>Depression</td><td>33</td><td>4.90%</td></tr>
<tr><td>Ataxia</td><td>2</td><td>0.30%</td></tr>
<tr><td>Fever</td><td>10</td><td>1.48%</td></tr>
<tr><td>Tremor</td><td>2</td><td>0.30%</td></tr>
<tr><td>Injection site warmth</td><td>1</td><td>0.15%</td></tr>
<tr><td>Dyspnea</td><td>1</td><td>0.15%</td></tr>
</table>
Additional observations were affirmed by study cooperator to be due to causes other than vaccination.
</td></tr>
</table>

Example 16.

<table>
<tr><td>Study Type</td><td>Safety</td></tr>
<tr><td>Pertaining to</td><td>ALL</td></tr>
<tr><td>Study Purpose</td><td>Demonstrate safety under typical field conditions</td></tr>
<tr><td>Product Administration</td><td>One dose</td></tr>
<tr><td>Study Animals</td><td>900 pigs, 3 months of age, at three different geographical locations</td></tr>
<tr><td>Challenge Description</td><td>Not Applicable</td></tr>
<tr><td>Interval observed after vaccination</td><td>Pigs were observed daily for 14 days following vaccination</td></tr>
<tr><td>Results</td><td>Numbers of pigs by site with specific clinical observation post-vaccination:
<table>
<tr><th>Clinical Observation</th><th>CA Site N=300</th><th>GA Site N=300</th><th>LA Site N=300</th></tr>
<tr><td>None*</td><td>255</td><td>300</td><td>100</td></tr>
<tr><td>Depression</td><td>0</td><td>0</td><td>100</td></tr>
<tr><td>Loss of condition</td><td>2</td><td>0</td><td>35</td></tr>
<tr><td>Anorexia</td><td>5</td><td>0</td><td>75</td></tr>
<tr><td>Unthrifty</td><td>5</td><td>0</td><td>65</td></tr>
<tr><td>Decreased appetite</td><td>0</td><td>0</td><td>65</td></tr>
<tr><td>Abnormal breathing</td><td>0</td><td>0</td><td>100</td></tr>
<tr><td>Cough</td><td>0</td><td>0</td><td>100</td></tr>
</table>
*For “none”a pig had to be observed without clinical observations for the entire 14 days of the study. Observations at the LA Site were generally attributed to study pigs unexpectedly experiencing an influenza outbreak at the beginning of the study.</td></tr>
<tr><td>USDA Approval Date</td><td>MMDDYYYY</td></tr>
</table>

Example 17:

Study Type	Efficacy
Pertaining to	Herpesvirus, Bovine (IBR)
Study Purpose	Efficacy against respiratory disease
Product Administration	
Study Animals	
Challenge Description	
Interval observed after challenge	
Results	Study data were evaluated by USDA-APHIS prior to product licensure and met regulatory standards for acceptance at the time of submission. No data are published because this study was submitted to USDA-APHIS prior to January 1, 2007, and APHIS only requires publication of data submitted after that date.
USDA Approval Date	March 20, 2002

Example 18:

Study Type	Efficacy
Pertaining to	Equine influenza
Study Purpose	Efficacy against Ohio 08 strain of equine influenza
Product Administration	
Study Animals	
Challenge Description	
Interval observed after challenge	
Results	This product class allows the manufacturer to update microorganisms in this vaccine under expedited procedures to respond to emerging needs. Abbreviated data to support influenza strain updates to the product composition were evaluated by USDA-APHIS and found to be acceptable based on regulations and policies at the time of approval. Full vaccination-challenge studies may not have been required for these updates.
USDA Approval Date	March 20, 2010

Example 19: Placeholder ISS for conditionally licensed platform products

Study Type	Efficacy
Pertaining to	Porcine circovirus type 2 (PCV2)
Study Purpose	Efficacy against subtypes of PCV2 other than PCV2a
Product Administration	
Study Animals	
Challenge Description	
Interval observed after challenge	
Results	This product was qualified as a production platform based on demonstrated efficacy against PCV2a, as shown in the product compilation summary for Establishment 999, Code 19K5.R6. As a platform product, the manufacturer may update the PCV gene insert in this vaccine under expedited procedures to respond to emerging needs. Abbreviated data to support these updates to the product composition were evaluated by USDA-APHIS and found to be acceptable based on regulations and policies at the time of approval. Full vaccination-challenge studies may not have been required for these updates. An identifier for the gene sequence variant found in a given serial (numbered batch) of vaccine is listed on product labeling.
USDA Approval Date	January 31, 2018

Example 20: Placeholder ISS for prescription platform products

Study Type	Safety
Pertaining to	Prescription Platform Product
Study Purpose	Safety
Product Administration	Intramuscular
Study Animals	Swine
Results	This product was qualified as a prescription production platform based on demonstrated safety as shown in the Product Summary for Establishment 999, Code 1234.56. As a prescription platform product, the manufacturer may update the gene insert in this vaccine under expedited procedures to respond to emerging needs per Veterinary Services Memorandum 800.214. Study data to support these updates were evaluated by USDA-APHIS and found acceptable based on regulations and policies at the time of approval. Additional safety studies may not have been required for these updates. An identifier for the gene sequence found in a given serial (numbered batch) of vaccine is listed on the product labeling.