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STLC ISS Data Requirements

Last Modified:

Data Requirements for Individual Study Summaries (ISSs)

Example ISSs for a variety of study designs are available on the CVB website. These are not meant to reflect the *only* way that study data can be presented, but they do provide acceptable examples. All presentations of study data must meet the following guidelines:

A. Efficacy Studies

1. Raw data: All efficacy ISSs must present *raw* study data. The ISSs are intended to meet the needs of a wide variety of readers.
2. Strive to present raw data in a meaningful, concise manner, but do not combine/collapse data so that information is lost.
    - Example: In example ISS #1, it would have been inappropriate to reduce the data for each calf to an overall yes/no outcome, as there were two parameters (virus and antibody) being evaluated. Information about individual calves would have been lost if those findings were combined into a single composite outcome.
3. Summarizations: *Limited* high-level summaries are permissible, but not required, to accommodate readers who do not wish to examine raw data. The following types of summarizations are allowed *in addition to* raw data:

- 5-number summaries are allowed for continuous numerical data, such as lung lesion scores or the duration of an event. Example ISS #5 shows this type of summarization.
- Totals are allowed for dichotomous or qualitative data, such as total mortalities or the number of animals meeting the criteria of a multi-factorial case definition. Express totals as the number affected over the total number (e.g., 9 of 25 died). Similarly percentages are also allowed as long as the numbers are included (e.g. 9 of 25 (36%)).
- It is permissible to include a "final classification" column at end of raw data to show the disposition for each animal (positive or negative). Example ISS #7 illustrates this type of summarization.
- **Do not include summarizations, such as averages or means. Do not include statistical analyses, such as prevented fractions or p-values.**

B. Safety Studies

For field safety trials (FST) according to VSM 800.204, a tabular presentation is recommended. The presentation may be in one or more tables to present the data adequately.

1. Account for every animal enrolled in the study. For the FST ISS, an animal is considered enrolled once it has received the first vaccination. Indicate the number of animals that completed the study (with or without an adverse event (AE)) and the number that did not complete the study (with or without an AE). In some circumstances it may be acceptable to provide this information in narrative form rather than in a table.
2. Present a table listing the AE by category.
    - The number of AEs may not match the number of animals experiencing AEs, since an animal may experience more than one AE.
    - AEs that are clearly considered to have a plausible cause other than vaccination may be included in a separate category. (Example: An animal dies a few days after vaccination due to accidental trauma). The explanation must be in the study report with adequate justification (i.e., definitive data) to rule out vaccination. Such AEs may be indicated as "affirmed by licensee to have a cause other than vaccination." Example ISS #15 shows this type of summary.

- Explanatory notes may be included to indicate circumstances that may affect the interpretation of the observations or where there is not a sufficient degree of certainty to designate the AEs as having a cause other than vaccination. In that case a short, concise explanation may be provided below the table. (Example: Pigs vaccinated with a Mycoplasma hyopneumoniae bacterin are part of a herd that experiences an influenza outbreak a couple of days later.) Example ISS #16 shows this type of summary.

3. Where appropriate, present a table of injection site swelling. Tabulate local injection site swelling by size and duration. Example ISS #10 shows this type of summary.
4. For poultry studies, include data for mortality, hatchability, and condemnation as required or on a case-by-case basis. Hatchability data are required for products administered in ovo. If the data are not available, make an explanatory notation . Mortality, hatchability, and condemnation data may be presented as percentages as long as total animal numbers are reported. Example ISS #14 shows this type of summary.

C. Exceptions for Historical Studies

The data requirements described in Sections V.A and V.B are expected for all summaries for studies conducted in 2017 forward. It is highly likely that studies of the past several years also will have the detail necessary to meet these requirements. The CVB recognizes that some older study reports may not have the detail necessary to meet all of the summary requirements, and these will be handled on a case-by-case basis to best present the available data.

If a full ISS will not be submitted for a study conducted prior to 2007, submit a placeholder ISS instead. Follow the format shown in Example ISS #17.

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Questions?

Questions may be directed to CVB.Single.Tier@usda.gov.

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