STLC Scope of Studies Required

Last Modified:

Scope of Studies Requiring Single Tier Summaries

1. **Prepare Individual Study Summaries for the following:**

    - Efficacy studies directly supporting licensure of a product
        - Host animal vaccination-challenge or field efficacy studies (short-term and duration of immunity): pivotal pre-license efficacy and any subsequent studies that change claims or instructions for use
        - Host animal vaccination-challenge to establish immunogenicity for the addition of new influenza subtypes in licensed products per VSM 800.111.
        - Codified tests highly correlated to host animal efficacy, which the CVB allows as fulfillment of pivotal efficacy requirements for certain agents (e.g., *Clostridium tetani*, and select other *Clostridium spp* serology)
    - Safety studies
        - Routine field studies (VSM 800.204)
        - Additional safety studies to support specific claims (e.g., safe for use in pregnant animals)
2. **Individual Study Summaries are typically *not* required for the following, unless specifically requested by the CVB:**

    - Reasonable expectation of efficacy for a conditional license

- Reference qualification studies that merely confirm the findings of prior pivotal efficacy
- Backpassage or shed/spread studies
- Proof-of-concept efficacy studies or studies conducted solely to fulfill requirements for foreign registration
- Component compatibility studies other than host animal vaccination-challenge (e.g., serological non-inferiority)
- Overdose safety studies
- Residue clearance studies
- Studies for products solely for official/emergency use by APHIS

3. **Full Individual Study Summaries are required for applicable studies submitted to the CVB on, or after January 1, 2007. Studies submitted prior to 2007 do not require a full summary, although one may be submitted voluntarily. Alternatively, a placeholder, as described in Section VI.C below, may be submitted. All product classes within the scope of single tier must have single-tier language on labeling, even if only placeholders are published on the CVB website.**

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Questions?

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

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