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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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