

## STATISTICS SECTION WORKFLOW

### **The Statistics Section (Stat)**

- The Statistics Section provides advice and services aimed at a rigorous understanding of data. Its perspective is founded on the full breadth of applied data sciences. Its team approach allows it to draw on a range of disciplines necessary to solve a problem.
- Stat has an obligatory role in the CVB licensing process. In addition to the CVB-PEL licensing staff, the section also serves the CVB laboratory staff and, when requested, CVB-IC. Through a Memorandum of Understanding with the National Veterinary Services Laboratories, the section provides services to NVSL.
- Stat collaborates with Reviewers on the review of study protocols and study reports and in developing policy for study design. Many of the relevant principles of study design are covered in other chapters of the Reviewers Manual, particularly 4.3 – Protocols, and the chapters on specific study types.
- Prioritization: Protocols – Stat aims to return protocols to the Reviewer within several days. Reports – ordinarily handled in the order received at CVB, regardless of when they are routed to Stat, if the submission is complete and clear.

### **Statistical Review**

An effective review process requires active collaboration between Reviewer and Statistician. This workflow is intended to foster that collaboration. Don't consider it a mechanical routing system, but a starting point for communication.

### **Workflow for items routed to Statistics**

#### 1. *Protocols.*

*Purpose.* It benefits everyone to deal directly with anything in the protocol that might potentially affect how the study is conducted and interpreted. Protocol review aims to encourage clarity in study design, which is critical to the validity of a study. A thorough protocol review with explicit comments to the firm may also lead to a more effective review of the study report later.

*Action.* When Stat provides comments to the Reviewer, they will indicate which are intended for the firm and which are for internal consideration. At times an outgoing enclosure for the firm may be prepared and discussed with the Reviewer. Unless officially transmitted to the firm, all such communications are considered internal discussions.

- #### 2. *Data.* All submissions requiring data must be accompanied by data files following the [CVB Data Guide](#). All data submissions will be checked for suitability, and unacceptable data submissions will be closed out of Stat. Stat may provide recommendations directly to the firm on how to improve their data submission, with copy to Reviewer.

3. *Reports – Routing to Statistics.* Please read the report first. Perhaps there is a showstopper and it should not be routed to Stat in the first place. Usually there is background information that is necessary for Stat to properly understand and handle the report.
  - 3.1. The Reviewer routes the report to Stat, providing
    - Completed summaries where applicable [REDACTED]
    - Background and related information.
    - Informational links in the ML to relevant previous submissions.
    - Reviewer decisions necessary for analysis that are clear.
  - 3.2. Shortly after receiving the report, Stat handles the report as follows.
    - Are the data in a CVB format? If not close loop. The Reviewer decides whether to close the submission or keep it open pending receipt of revised data files. Usually Stat will email the firm with advice about the data format, copying the Reviewer.
    - Has the Reviewer provided enough info for Stat to proceed? If not, request info from the Reviewer. If still not provided close loop.
    - If data and info suitable, proceed to Section 4.
4. *Reports – Assessment by Statistics.* Stat will select one of the options below.
  - 4.1. Expedited analysis within an early time frame.
    - 4.1.1. If Stat determines that the report’s statistical analysis appears adequate, at least in part, it might be possible to expedite the Stat response to the Reviewer.<sup>1</sup> In that case, Stat will provide an assessment that may use the suitable parts of the report’s statistical analysis to efficiently supplement preparation of the Stat evaluation. Reviewers may then use the statistical information provided in the Stat assessment, regardless of origin, but not other statistical analyses or summaries from the report, which may be unsuitable.
    - 4.1.2. Certain types of submissions are intended for limited processing only, if suitably prepared by the submitter. For example, observational field safety trials (FST) according to VSM 800.204 with electronic data submitted according to the CVB Data Guide will normally be rapidly returned to the Reviewer with summaries prepared by immediate machine processing. (Other safety studies with more complex designs do not fall in this category.)
  - 4.2. Held for routine Stat analysis. Time frame depends on workload.
    - 4.2.1. Any report not clearly fitting within Section 4.1.
    - 4.2.2. Reports of unusual study types or with other non-routine features.<sup>2</sup>
5. *Technical advice.* When seeking technical advice from Stat, firms should do the following.
  - *Data preparation.* First check the [CVB Data Guide](#). If there are still questions about data format, contact Stat before submission.

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<sup>1</sup> To be suitable for review purposes under CVB guidelines, a firm’s statistical treatment must follow the guidance in VSM 800.200, VSM 800.202, other relevant guidance documents, and other Stat guidance. Graphical or tabular displays of the findings that are informative and appropriate may help expedite the review process, but irrelevant or misleading presentations can be distracting and hamper review. Use of the software developed by Stat is not required but may be helpful.

<sup>2</sup> Examples include natural exposure field efficacy studies or novel assay validation studies.

- *Study design.* First check with your Reviewer. The Reviewer may direct the firm to Stat for discussion about certain aspects of study design.
  - *Statistical analysis.* Before submission, Stat will consider general inquiries from the firm's statistician about their proposed statistical analysis. We cannot, however, engage in actual review or analysis before submission. Such informal discussions of methodology carry no implications about the ultimate disposition of the submission.
  - *Contacting Stat.* The CVB Statistics Section may be reached at [CVB.Data.Help@aphis.usda.gov](mailto:CVB.Data.Help@aphis.usda.gov)
6. *Internal communication.* Unless officially transmitted to the firm, all communications between Statistician and Reviewer are treated as internal discussions.